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Centers for Medicare & Medicaid Services

REPORT TO CONGRESS

Fiscal Year 2023

The Centers for Medicare & Medicaid Services' COVID-19 Public Health Emergency Response and Use of Section 1135 Waivers and other Flexibilities

January 2025

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I. Executive Summary

On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS) declared under section 319 of the Public Health Service Act that the Coronavirus disease 2019 (COVID-19) presented a public health emergency (PHE) for the United States that existed since January 27, 2020, and on March 13, 2020, the President declared COVID-19 a national emergency. These two declarations authorized the HHS Secretary to use section 1135 of the Social Security Act (the Act) to waive or modify specified statutory and regulatory requirements related to Medicare, Medicaid, and the State Children's Health Insurance Program (CHIP), as the Centers for Medicare & Medicaid Services (CMS) determined need. The purpose of section 1135 of the Act is to enable the HHS Secretary to ensure that sufficient health care items and services are available to Medicare, Medicaid, and CHIP beneficiaries, and that health care providers that furnish these services in good faith may be paid and exempted from possible sanctions. Waivers issued under section 1135 are restricted by geography, to the area covered by the PHE, and time-limited, until the conditions that merit a waiver no longer apply or no later than expiration of the PHE.

On May 11, 2023, the HHS Secretary ended the COVID-19 PHE. Pursuant to section 1135(f) of the Act, the HHS Secretary must provide a report to the Congress within one year of the end of the emergency under which section 1135 authorities were invoked. As required by section 1135(f), this report covers: 1) the approaches used to accomplish the purposes of the waiver; 2) an evaluation of these approaches; and 3) recommendations for improved approaches. While this report primarily focuses on section 1135 waivers, other flexibilities such as statutory changes and sub-regulatory guidance are discussed as they aid in understanding areas of need that could not be accomplished through section 1135 waiver authority and may be important for consideration in the evaluation of future approaches. The totality of these efforts are referred to as flexibilities and/or waivers throughout this report.

Approaches used to accomplish section 1135 purposes. Traditionally, CMS uses emergency authority under section 1135 of the Act to waive or modify certain specified requirements under titles XVIII, XIX, XXI, and XI of the Act (hereinafter called "Medicare and Medicaid 1135 waivers") to ensure that beneficiaries of the Medicare and Medicaid programs have access to services during a national emergency and that providers have the flexibility to provide and be paid for these services. CMS has standard operating procedures for emergency declarations that have been used multiple times in the past to assist states and health care providers managing regional emergencies. There are two ways that section 1135 waivers are issued: Blanket waivers (i.e., no request needed and made available across the emergency area) and individual waivers (i.e., states, providers, and suppliers apply, and made available for a specific geographic area). In the past, after declaration of a disaster, CMS has leveraged a list of pre-scripted section 1135 model blanket waivers that covered the most frequent requests to expedite assistance. The model waiver list was informed by CMS' experience processing about 4,000 section 1135 waiver requests annually, most related to hurricanes, tornadoes, and wildfires.[1] Additional information on waivers can be found at Waivers & flexibilities | CMS.[2] While these processes were immediately initiated at the beginning of the COVID-19 PHE, the volume and speed of policymaking greatly increased and it soon became apparent that the COVID-19 PHE was an unprecedented event that was national in scope and that the science related to prevention and control of the virus was rapidly evolving, presenting new challenges.

[1] CMS regional offices processed section 1135 waiver requests manually and, as a result, the processing varied depending on a regional office's geographic location and exposure to a given PHE. For example, a regional office in a geographic area with less exposure to natural disasters, such as hurricanes, tornadoes, or wildfires, and fewer waiver requests related to such weather phenomena, might process waiver requests using a simple word processing program. In contrast, a regional office in a geographic area with greater exposure to these types of natural disasters and more waiver requests might use a relational database management program to sort, categorize, track, and manage waiver requests.
[2] Centers for Medicare & Medicaid Services. https://www.cms.gov/about-cms/what-we-do/emergency-response/how-can-we-help/waivers-flexibilities. Accessed September 17, 2024.

The approaches used to manage the growing challenges included: 1) modifying existing rules through waivers and flexibilities, including section 1135 waivers; 2) creating new or revising existing rules through rulemaking; and 3) clarifying existing rules through sub-regulatory guidance. The use of each approach was determined after careful consideration of the circumstances of the emergency issue and/or action required. Waivers and sub-regulatory guidance can be implemented relatively quickly, but their use is limited to modifying or clarifying existing policies, respectively. Rulemaking is more difficult and time-consuming but has a broader impact and can reflect new policy. Over the duration of the PHE March 2020- May 11, 2023, CMS processed over 273,678 section 1135 waiver requests, issued 160 blanket waivers, and processed 6 emergency regulations.

Given the volume of policy and operational changes required to address the COVID-19 PHE, a whole-of-CMS effort was needed to facilitate the agency's response. Like many in the nation, the CMS staff were called upon to carry out extraordinary service. For Medicare, CMS established the COVID-19 Workgroup, led by the Administrator as the primary structure for decision-making and cross-agency communication. To expedite decision-making, a cross-agency Medicare Waiver Request Team, along with a Rapid Response Team, and a group of senior CMS clinicians reviewed and provided recommendations on waiver requests to the COVID-19 Workgroup.

The Center for Medicaid and CHIP Services (CMCS) established and led a Medicaid section 1135 Response Team which was tasked with reviewing state-submitted Medicaid and CHIP section 1135 waiver requests, collaborating with subject matter experts, and working with CMCS leadership and the Administrator to expedite approvals. The variation across state Medicaid programs meant that challenges related to the PHE likely would not be met uniformly. As such, CMCS made section 1135 waivers available to states, which could then determine the types of waivers to request and, once approved, when and how to implement them. CMCS also issued updated toolkits (e.g., state disaster relief toolkits) and checklists with information on available flexibilities for states.

Collectively, the teams considered the breadth of CMS programs and policy areas, including Medicare, Medicaid, CHIP, and the Marketplace, taking into account issues of provider payments, program and plan oversight, health and safety, health equity, quality measurement, local consumer and partner experience, technology and infrastructure requirements, and data and analytics, all in the midst of an emergency. CMS aimed to ensure an agency-wide approach responsive to the needs of communities, health care professionals, and consumers in every U.S. state, territory, District of Columbia, and tribal nation.

Evaluation of approaches used to accomplish section 1135 purposes. Throughout the PHE, CMS added and terminated blanket and individual waivers and continuously assessed their necessity, impacts on safety and quality, and potential program integrity concerns.[3] Given the nature of blanket waivers, there were data limitations in monitoring and evaluating policy changes to determine whether the waivers were still needed and having their intended impacts; however, CMS maintained close contact with states and the provider and supplier communities to determine the effectiveness of the flexibilities.

As the PHE continued, CMS recognized the need to prepare the health care system for the end of the PHE and of related section 1135 waivers and flexibilities. CMS developed the *Supporting Health Care System Resiliency Cross-Cutting Initiative* to reestablish certain standards and requirements with the ending of the COVID-19 PHE and to ensure CMS preparedness for future emergencies. CMS reviewed all flexibilities put in place throughout the PHE to assess the impact of ending each waiver and flexibility and to identify flexibilities that could be made permanent where possible. CMS implemented systematic and comprehensive communications to ensure that interested parties were kept informed of the flexibilities that would end or

[3] Statutorily, CMS is permitted to evaluate and assess waivers based on necessity, maintenance of health care safety and quality, and program integrity. As such, CMS continuously assessed waiver effectiveness, appropriateness, and necessity based on these criteria. CMS sought and informed our policy considerations with feedback from health care professionals, associations, individuals, Members of Congress, local community organizations, state, local, and tribal government, and other partners involved in health care delivery and infrastructure.

remain in place and how to prepare to ensure continuity of services. The CMS COVID-19 Workgroup continued to meet, led by the then new Administrator who approved the final decisions related to section 1135 waiver activity.

Many areas regarding Medicare, Medicaid, CHIP, and the Marketplace required attention from CMS during the pandemic. In this report, we primarily focus on six key areas for which waivers and flexibilities were necessary, including: 1) vaccines and therapeutics; 2) testing; 3) telehealth; 4) emergency reporting; 5) surge capacity; and 6) long-term care[4] (LTC) facilities. For each area, this report summarizes CMS' policy response and synthesizes external feedback gathered from peer-reviewed literature, policy briefs, government reports and journal publications, letters to HHS and CMS, statements from professional associations, interviews conducted with professional associations, and general listening sessions. This report also includes discussions and recommendations on several cross-cutting issues such as workforce capacity, health care disparities, quality improvement and patient safety, and process improvements in the execution of section 1135 waivers and flexibilities.

CMS also took actions to identify and address program integrity risks related to COVID-19 PHE waivers and flexibilities. CMS identified potential risks and vulnerabilities for the waivers and flexibilities, tracked them, and developed mitigation strategies. Some program integrity issues that CMS identified included billing for medically unnecessary respiratory pathogen panel testing in an outpatient setting, fraudulent billing of over-the-counter COVID-19 tests that were temporarily covered under a demonstration, and exploitation of telehealth flexibilities. CMS opened investigations on individuals and entities who took advantage of the flexibilities and took steps to recover overpayments. CMS also took numerous administrative actions, including payment suspensions and revocation of billing privileges of providers. In addition, CMS partnered with federal law enforcement to investigate and prosecute fraud schemes, particularly those connected to identity theft and vaccine distribution.

The agency also conducted independent post-pandemic interviews with providers to determine the perspective of external parties such as hospitals, nursing homes, clinicians, and other provider types. Overall, respondents applauded CMS for addressing the needs of providers by issuing waivers on a timely basis and providing clarifications about waivers. Providers also gave valuable feedback regarding improvements to consider for future emergencies and to ensure a resilient health care system. Many of the comments centered on the six key areas identified above and are expanded upon in this report.

Conclusion and recommendations for the future regarding section 1135 waivers. Waivers provided critical flexibilities during the COVID-19 PHE and highlighted the need for infrastructure to support a rapid and nimble response in future PHEs. Given the nature of the pandemic, section 1135 waiver authority alone was not sufficient to address the nation's critical needs. Congressional action and emergency regulations were necessary. Coordination of all policy levers will be important in future events of this magnitude. The COVID-19 PHE revealed opportunities across the health care system to streamline regulations; enhance communications, incorporate advances in technology; align programs within and outside of government; and address underlying disparities in health care outcomes, access, and quality. As a result of multiple inputs described throughout this report, CMS identified the following recommendations that will be considered in the future when issuing waivers and flexibilities to support a resilient health care system (to the extent permissible under federal and state law):

1. **Maintaining access to care and provider capacity through telehealth**: Explore expansion of Medicare telehealth opportunities that will provide the ability to increase workforce capacity and support health care providers in delivering and receiving payment for services delivered using telehealth.
2. **Sustaining workforce capacity during a PHE**: Examine regulations to determine if there are areas that allow for strengthening workforce capacity through expansion of the scope of practice for clinicians other than physicians.

[4] Long-term care, skilled nursing facility, nursing home, and nursing facility are used interchangeably throughout this report.

3. **Strengthening the nation's health, safety and quality infrastructure that will be sustainable and beneficial during a national emergency**: Increase preparedness for future public health emergencies and resiliency in the health system.
4. **Protecting the Underserved:** Ensure policy development and implementation activities consider and protect underserved populations.
5. **Supporting health system capacity and resiliency**: Continue to explore and educate facilities on flexibilities available within CMS regulations to expand facility surge capacity during and outside of a PHE.
6. **Enhancing data monitoring systems:** Consider ways to collect authorized data in an efficient manner to inform emergency efforts, particularly when issuing blanket waivers.
7. **Applying administrative processes:** Identify and implement process improvements in the execution of section 1135 waivers during a PHE.

The report in its entirety highlights specific background information, lessons learned, a summary of feedback from external parties, and recommendations to prepare for future PHEs.

II. Background

COVID-19 emerged in the United States early in 2020, with rapid transmission and significant risk to vulnerable American populations, such as older adults and individuals with chronic conditions, that posed an unprecedented challenge to the U.S. health care system. The virus was the first modern global pandemic on scale with the Great Influenza pandemic of 1918–1920 and would be declared a public health emergency (PHE). In response to the COVID-19 PHE, CMS took action to ensure delivery of and access to health care to address the pandemic and the overall health care needs of Americans. CMS used emergency waivers, flexibilities, and regulatory authorities, chiefly pursuant to section 1135 of the Act, as amended (codified at *42 U.S.C. 1320b–*5). The CMS response under section 1135 addressed the needs of nearly 61.6 million Medicare beneficiaries, 64 million Americans enrolled in Medicaid, 6.6 million enrolled in CHIP, and 11.4 million people with coverage through the Marketplace, as the pandemic's impact disrupted health care delivery and resulted in widespread decreases in access and utilization.[5,6,7,8] As required by section 1135(f) of the Act, this report covers: 1) the approaches used to accomplish the purposes of the waiver, 2) an evaluation of these approaches, and 3) recommendations for improved approaches. While this report primarily focuses on section 1135 waivers, other flexibilities such as statutory changes and sub-regulatory guidance are discussed as they aided in understanding areas of need that could not be accomplished through section 1135 waiver authority and may be important for consideration in the evaluation of future approaches. The totality of these efforts is referred to as flexibilities and/or waivers throughout this report.

A. Overview of the COVID-19 PHE: Proclamation and Determination of National and Public Health Emergencies Due to the Effects of COVID-19

In response to the spread of COVID-19, the President, Congress, and HHS acted to protect Americans and to reduce disruptions to the health care system.[9] On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization declared COVID-19 a "Public Health Emergency of International Concern." On January 31, 2020, pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d), the HHS Secretary declared a PHE in the United States to support the nation's response to

[5] Centers for Medicare & Medicaid Services, "December 2020 and January 2021 Medicaid and CHIP Enrollment Trends Snapshot," Accessed January 9, 2024.
[6] CMS Medicare Enrollment Dashboard, "Interactive Tools Page | CMS Data," accessed December 18, 2024.
[7] Centers for Medicare & Medicaid Services, "Health Insurance Exchanges 2020 Open Enrollment Report," Accessed December 17, 2024.
[8] Assistant Secretary of Planning and Evaluation, "Impact of the COVID-19 Pandemic on the Hospital and Outpatient Clinician Workforce," May 3, 2022.
[9] Multiple federal agencies were involved in the response to the COVID-19 pandemic, including Federal Emergency Management Agency, Department of Homeland Security, CDC, HRSA, and the National Institutes of Health, among others.

COVID-19 that existed since January 27, 2020. On March 11, 2020, the World Health Organization declared COVID-19 a pandemic, and on March 13, 2020, the President declared the COVID-19 pandemic a national emergency pursuant to the National Emergencies Act.[10]

From 2020 until early 2023, the HHS Secretary renewed the PHE declaration on a quarterly basis for three years, a total of 13 times. The first renewal of the determination of a nationwide PHE as a result of the COVID-19 pandemic was on April 21, 2020. On February 11, 2023, the HHS Secretary provided a 90-day notice to governors that the PHE would end on May 11, 2023.[11,12] As the PHE ended and states worked to resume routine operations, CMS focused on ensuring an orderly transition and promoting continuity for Medicare, Medicaid, CHIP and the Marketplace.

B. Legislative Authorities and Use

Section 1135 of the Act authorizes the HHS Secretary to waive or modify specified statutory and regulatory requirements related to the provision of health care services under Titles XVIII (Medicare), XIX (Medicaid), and XXI (CHIP) of the Act[13] as determined by CMS. Section 1135 waivers are actions taken by the HHS Secretary in exercising section 1135 authority.[14] The purpose of section 1135 waivers:

> *"is to enable the Secretary to ensure to the maximum extent feasible, in any emergency area and during an emergency period … that sufficient health care items and services are available to meet the needs of individuals in such area … and that health care providers that furnish such items and services in good faith, but that are unable to comply with one or more requirements, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse."*[15]

The HHS Secretary can exercise section 1135 waiver authority when two conditions are met—the President has issued a disaster declaration (pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act), and the Secretary has determined that a PHE exists under section 319 of the Public Health Service Act.[16]

To accomplish the purpose of section 1135 waivers during a declared national emergency or disaster, Congress delegated broad authority to the HHS Secretary as follows:

> *"To the extent necessary*[17] *to accomplish the purpose specified in subsection (a), the Secretary is authorized … to temporarily waive or modify the application of, with respect to health care items and services furnished by a health care provider … in any emergency area … during any portion of an emergency period, the requirements of subchapters XVIII, XIX, or XXI, or any regulation thereunder[.]"*[18]

As part of the Secretary's responsibility to notify Congress following the PHE determination that waivers or modifications of requirements under section 1135 of the Act may be needed, the "Secretary provides a

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[10] Executive Office of the White House, "Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak," March 13, 2020.
[11] Department of Health and Human Services, "Letter to US Governors from HHS Secretary Renewing COVID-19 PHE for 90 Days," February 11, 2023.
[12] Department of Health and Human Services, "HHS Secretary Xavier Becerra Statement on the End of the COVID-19 Public Health Emergency," May 11, 2023.
[13] Pursuant to 42 U.S.C. § 1320b-5(7), the HHS Secretary is also authorized to temporarily waive or modify sanctions and penalties that arise from noncompliance with certain requirements of the Health Insurance Portability and Accountability Act of 1996.
[14] 42 U.S.C. § 1320b-5
[15] 42 U.S.C. §1320b-5(a)
[16] 42 U.S.C. § 1320b-5(g)
[17] The HHS Secretary's notice to waive or modify the requirements under Section 1135 includes that this authority applied "only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services."
[18] 42 U.S.C. § 1320b-5(b)

certification and advance written notice to the Congress … before exercising the authority," which includes language delegating the determination of "extent necessary" for waivers to CMS. The CMS Administrator is typically responsible for implementing section 1135 waivers to meet the needs of individuals enrolled in Medicare, Medicaid, and CHIP.[19]

Once the conditions have been met to permit the exercise of the section 1135 waiver authority, the Administration for Strategic Preparedness and Response[20] convenes relevant operating divisions and subject matter experts to determine whether to recommend the Secretary invoke section 1135 waiver authority and to determine the need and scope for modifications to existing requirements, if appropriate. Administration for Strategic Preparedness and Response, CMS, and the relevant operating divisions may collect needed information, which may include requests from governors' offices, feedback from individual health care providers and associations, solicitations to regional or field offices for assistance, information obtained from the Secretary's Operation Center, and key subject matter experts from operating divisions.[21]

1. Section 1135 Authorities

Section 1135 authorities cover a range of waivers or modifications of federal requirements concerning participation, payment, and health care delivery. Examples of requirements that the Secretary may waive or modify during an emergency include but are not limited to:[22, 23]

- **Conditions of participation for providers,** including certification requirements and program participation.
- **State licensure requirements for practitioners,** enabling practitioners to deliver equivalent services beyond the state(s) in which they were licensed.
- Modification of "**deadlines and timetables for performance** of required activities."
- **Telehealth**, related to Medicare payment requirements under section §1834(m) and certain Medicaid requirements. In addition to section 1135 waivers, at least two statutory changes were enacted at the start of the PHE that "expand[ed] the Secretary's authority to temporarily waive or modify application of certain Medicare requirements" related to telehealth.[22]
- **Modification of sanctions** for certain violations of the physician self-referral law (Stark Law). In addition to the Section 1135 waiver authority, section 1812(f) of the Act authorizes the Secretary to provide alternative criteria for Medicare coverage of a skilled nursing facility (SNF) stay in the absence of a qualifying hospital stay, as long as such coverage does not increase overall program payments and does not alter the SNF benefit's "acute care nature," (that is, for short-term, intensive care). Specifically, this authority allows for patient discharge to a SNF from a hospital, to enable greater access to a hospital setting for other patients.[24] In addition, for certain beneficiaries who exhausted their SNF benefits, the Secretary, using the discretion set out under section 1812(f) of the Act, permitted one-time renewed SNF coverage without first having to start and complete a 60-day "wellness period" (i.e., the 60-day period of non-inpatient status typically required to end a current

[19] https://aspr.hhs.gov/legal/1135-Waivers/Pages/covid19-13March20.aspx; see also United States Government Accountability Office, "Medicare and Medicaid COVID-19 Program Flexibilities and Considerations for Their Continuation," May 19, 2021.
[20] On July 22, 2022, the HHS Secretary announced the decision to elevate the Office of the Assistant Secretary for Preparedness and Response from a staff division to an operating division, taking on the new name of the Administration for Strategic Preparedness and Response, https://www.hhs.gov/about/news/2022/07/22/hhs-strengthens-countrys-preparedness-health-emergencies-announces-administration-for-strategic-preparedness-response.html.
[21] CMS, "https://www.cms.gov/medicare/coverage/telehealth" Accessed May 9, 2024
[22] Administration for Strategic Preparedness and Response, "1135 Waivers," Accessed January 10, 2024.
[23] CMS, "Medicare Fee-For-Service Emergency and Disaster Frequently Asked Questions (FAQs) Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only With a Section 1135 Waiver," August 1, 2023.
[24] Administrator CMS, Findings Concerning Section 1812(f) of the Act in Response to the Effects of Tropical Storm Barry in the State of Louisiana in 2019, July 12, 2019.

benefit period and renew SNF benefits). Throughout this document, we refer to the authority granted at section 1812(f) as a "Section 1135 authority" for convenience, but the authority to waive requirements granted by section 1812(f) is a separate and independent authority that is not legally contingent on the authority at section 1135 of the Act. However, CMS has historically used the authority at section 1812(f) of the Act simultaneously with the authority at section 1135 of the Act in response to a declared PHE.

2. Brief History of Typical Uses of Section 1135 Waiver Authorities

During a PHE, CMS can issue either individual or blanket section 1135 waivers. In either case, the HHS Secretary's use of section 1135 authority acknowledges that such waivers and flexibilities are to be exercised "only to the extent necessary" to ensure that health care items and services are available, as determined by CMS, which considers the needs of states and territories and affected communities before issuing section 1135 waivers.

A given individual waiver specifies a geographic area, which may be any area equal to or smaller than the entire declared emergency area—such as a single city or location—but it does not cover areas outside the emergency area.[25] For example, hurricanes and other disasters often represent an impact of known duration and geographic area, while PHEs involving disease outbreaks may be more diffuse or dispersed events. A state or geographic region may see limited impact, while a particular city or community may experience a severe outbreak. Such geographic variation may make it hard to define a quantifiable trigger point.[26]

Prior to the COVID-19 PHE, most disaster or emergency-related PHEs were short-term and defined by geography. The CMS regional offices in the locality of the disaster or emergency generally processed section 1135 waiver requests; as a result, processing varied depending on a regional office's location and exposure to a given PHE. For example, 1135 waivers were issued for certain areas after hurricanes and natural disasters. Under section 1135 of the Act, CMS can issue several blanket waivers as a result of a disaster or emergency (Hurricanes & tropical storms | CMS)[27]

Blanket waivers are made available across the emergency area and do not need to be requested. These waivers help to ensure access to care for beneficiaries affected by an emergency when CMS has determined that all similarly situated providers in an emergency area need such a waiver or modification. Blanket waivers have the benefit of speed with less administrative burden during the time of crisis but limit CMS' ability to monitor how waivers are being leveraged in the field, as health care providers and states do not need to request blanket waivers or to notify CMS regarding waiver use. An individual or specific section 1135 waiver determination can be requested if there is no blanket waiver available or in effect to address specific services, requirements, or flexibilities that would benefit a provider. As part of its review, CMS determines whether a provider's individual request would apply to similar providers and should be approved as a blanket waiver.

In the past, after declaration of a disaster, CMS has utilized section 1135 template blanket waivers that covered the most frequent requests. This pre-drafted model waiver list was informed by CMS experience processing about 4,000 section 1135 waiver requests annually, most related to hurricanes, tornadoes, and wildfires.[28] The model waivers needed only minor changes in language for each event. The model waiver list

[25] CMS, "Medicare Fee-For-Service Emergency and Disaster Frequently Asked Questions (FAQs) Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only With a Section 1135 Waiver," August 1, 2023, Question 21.
[26] Ibid.
[27] Centers for Medicare & Medicaid Services. Hurricanes & tropical storms | CMS. Accessed September 17, 2024.
[28] CMS regional offices processed section 1135 waiver requests manually and, as a result, the processing varied depending on a regional office's geographic location and exposure to a given PHE. For example, a regional office in a geographic area with less exposure to natural disasters, such as hurricanes, tornadoes, or wildfires, and fewer waiver

has enabled CMS to rapidly make the required determination and adjust the language to loosen requirements that would otherwise apply. For example, if patients evacuated to a safe location due to a tornado, CMS, given emergency flexibility, authorized replacement of durable medical equipment destroyed within the emergency area.

Historically, CMCS granted individual section 1135 waivers to states to aid in their response to PHEs. Typically, CMCS collaborated internally to provide technical assistance to states immediately following an event, including determining the appropriate authorities needed to ensure beneficiary access to services and timely payment to providers. States would request section 1135 waivers that applied only to the portion of the affected state and to those affected by the disaster. During the COVID-19 PHE, states evaluated the need for Medicaid and CHIP section 1135 waivers more generally and then made specific requests to CMCS. As noted earlier, once waivers were approved, states had the flexibility to monitor local conditions and apply a given waiver on an as-needed basis.

Apart from section 1135 authority, states also have significant flexibility under the title XIX of Act and implementing regulations and under section 1115 of the Act to design and implement how their Medicaid programs and CHIPs operate, including in times of emergencies.[29] For example, states can request section 1915(b) and 1915(c) waivers to target specific populations or use section 1115 demonstration authority to test new or innovative approaches to address the health care needs of beneficiaries. During a PHE, states may also make additional time-limited changes to their Medicaid program or CHIP through a Disaster Relief State Plan Amendment (SPA). In addition, states may request temporary changes to their section 1915(c) home and community-based services (HCBS) waiver programs by submitting Appendix K amendments or amend a section 1115 demonstration. The Appendix K amendment was developed to reduce states' administrative burdens during a crisis by enabling states to rapidly modify or add services provided through section 1915(c) HCBS waivers and section 1115 demonstrations with 1915(c)-like services. Appendix K is a standalone appendix for section 1915(c) waivers or attachment for section 1115 demonstrations that states may use to request temporary amendment(s) to covered services, provider qualifications, and other requirements set forth in CMS-approved section 1915(c) waivers or 1115 demonstrations for the duration of an emergency situation in order to respond to an emergency. CMS also may use section 1135 waiver authority to waive or modify certain Medicaid or CHIP regulations.

Additionally, adjustments were made to certain Centers for Medicare & Medicaid Services (CMS) Innovation Center Models to address the COVID-19 public health emergency (PHE), specifically around financial methodologies, quality reporting, and model timelines. CMS used the following principles to determine which changes were appropriate: Utilizing flexibilities that already exist in current model design, continuing sufficient financial incentives that encourage higher quality outcomes to participate in value based arrangements, ensuring equity and consistency across models, aligning as much as possible with national value based and quality payment programs, minimizing risk to both model participants, the Medicaid program, and the Medicare Trust Funds, minimizing delays in new model implementation while providing additional opportunities for participation in new models, minimizing reporting burden, as well as complementing and building off of new CMS COVID-19 PHE flexibilities as outlined in regulation and waivers.

III. Required Elements of Section 1135(f) Report to Congress

Section 1135(f) of the Act sets out three requirements for the HHS Secretary's report to Congress as follows:

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requests related to such weather phenomena, might process waiver requests using a simple word processing program. In contrast, a regional office in a geographic area with greater exposure to these types of natural disasters and more waiver requests might use a relational database management program to sort, categorize, track, and manage waiver requests.

[29] Under the Social Security Act, the territories are considered states for the purposes of Medicaid and CHIP, unless otherwise indicated (§ 1101(a)(1)).

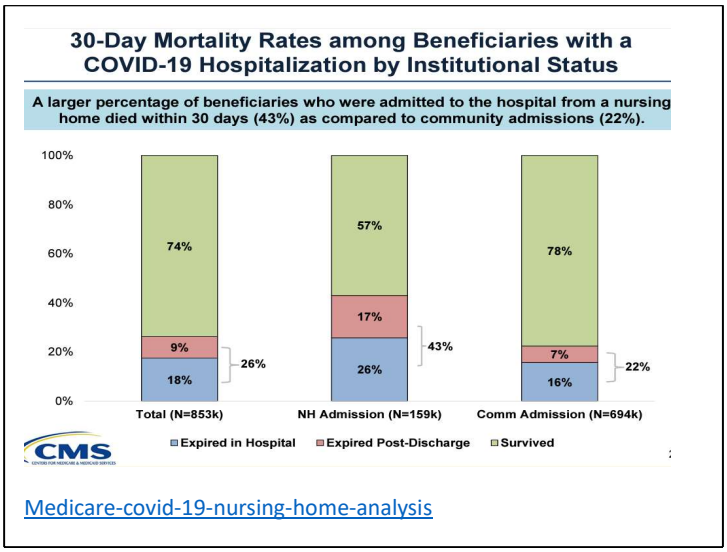
"Within one year after the end of the emergency period in an emergency area in which the Secretary exercised the authority provided under this section, the Secretary shall report to the Congress regarding the approaches used to accomplish the purposes described in subsection (a), including an evaluation of such approaches and recommendations for improved approaches should the need for such emergency authority arise in the future."[30]

Each of the three statutory requirements—A.) the approaches used to accomplish the subsection (a) purposes; B.) an evaluation of such approaches; and C.) recommendations for improved approaches for future emergencies—is discussed in the following sections.

A. Approaches Used to Accomplish Section 1135 Purposes for the COVID-19 Pandemic

CMS received an unprecedented number of Medicare and Medicaid waiver requests at the start of the COVID-19 PHE, reflecting the unique nature of COVID-19 and the lack of geographic boundaries for the emergency. Within the first two weeks of the COVID-19 PHE, CMS received more than 30,000 section 1135 Medicare and Medicaid waiver requests from providers and states —almost eight times the number of requests typically received in an entire year. Within the scope of section 1135 authorities, CMS aimed to issue waivers and flexibilities that would address the unmet needs of all. CMS also worked to address the issues of the underserved and most vulnerable whose needs were even more pronounced during the pandemic given social risk factors that adversely affect health.[31]

Particular attention was given to those in LTC settings given the vulnerability of the residents and the initial case and death rate in congregate settings.[32] While LTC residents accounted for about 2 percent of the Medicare population, in 2020 they comprised about 22 percent of all COVID-19 cases.[33] A larger percentage of beneficiaries who were admitted to the hospital from a nursing home died within 30 days (43 percent) as compared to community admissions (22 percent).



In the early phase of the COVID-19 PHE, CMS prioritized emergency response above day-to-day tasks, requiring extensive internal coordination and engaging multiple HHS operating divisions and other federal agencies. Intra-agency coordination centered on the COVID-19 Workgroup, led by the CMS Administrator

[30] 42 U.S.C. § 1320b-5(f)
[31] Center for Budget and Policy Priorities. New Data on Hardship Underscore Continued Need for Substantial COVID Relief. (December 2, 2020)
[32] CMS, "Coronavirus Waivers and Flexibilities, Waivers and Flexibilities for Health Care Providers," Last modified September 6, 2023. https://www.cms.gov/coronavirus-waivers
[33] Ibid.

and a group of leaders from across CMS centers that met daily in the beginning to make policy decisions. CMS also coordinated with agencies across HHS including the Federal Emergency Management Agency (FEMA), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) to leverage existing relationships and broker new linkages between programs and teams to strengthen the response.

In the case of Medicare, the first group of blanket waivers were issued on March 13, 2020, and as noted earlier, included flexibilities similar to those previously issued in response to earlier PHE declarations. However, CMS moved quickly to issue additional blanket waivers and flexibilities to address such needs as suspending provider reporting requirements, expanding services delivered using telehealth, and permitting the use of auxiliary space within hospitals to address surge capacity. As of May 2023, CMS received and processed 273,678 COVID-19 section 1135 waiver requests related to Medicare.[34] Most requests were submitted as individual provider waiver requests to CMS; over 233,000 were evaluated and covered under section 1135 blanket waivers. (See Appendices B through E for detailed lists of section 1135 waivers in the Medicare program that accomplished the purposes of section 1135(a) in four key areas: vaccines and therapeutics, COVID-19 testing, telehealth, and LTC facilities.) The following chart displays the specific types of waivers requested over the course of the PHE.

Top Waiver & Flexibility Request Types

1135 Waiver Request Type	Totals
Part A or B Provider Locations (Billing)	1,414,89
Home Health Agency (HHA): Timeframe for OASIS Transmission	86,921
Minimum data Set (MDS): Survey, Certification, Quality and Enforcement	85,090
Conditions of Participation (COP)	7,240
LTC Facilities (SNFs and NFs) – Training and Certification of Nurse Aides	6,260
Alternate Treatment Sites	4,661
EMTALA: Survey, Certification, Quality and Enforcement	3,434
Life Safety Code (LSC)	1,879
Skilled Nursing Facility (SNF): 3-day Prior Hospitalization	1,440

The circumstances of the request or needed action dictated the approach. For example, while rulemaking can be a more time-consuming process than the issuance of waivers, with a longer clearance timeline, rules have longer and broader impact, can reach issues, such as payment, that are not waivable under section 1135, and can reflect new policy. In contrast, waivers and flexibilities could be implemented more quickly but would be limited to modifying existing policies. Sub-regulatory guidance would be the fastest mechanism because it clarifies existing policies but is intended solely to interpret, as opposed to change, existing policies.

[34] Submissions for section 1135 waiver requests were permitted through the last day of the PHE (May 11, 2023). As of the final day, 16 additional requests were received for a total of 273,694. CMS resolved a total of 273,678 section 1135 waiver requests.

Similarly, state Medicaid agencies evaluated the impact of the COVID-19 PHE and requested that the Secretary approve section 1135 Medicaid waivers and other flexibilities the states determined to be necessary to ensure beneficiaries' continued access to services without disruption.

1. CMS' Operational Approach to Processing Section 1135 Waivers

In this section, we describe the top-level processes and coordination that CMS used to consider and issue section 1135 waivers and COVID-19 PHE-related flexibilities, for Medicare and for Medicaid and CHIP.[35] As previously noted, the nature of the state-federal partnership for Medicaid and CHIP meant that CMCS worked closely with states, territories, and tribes to determine needed authorities; in addition to section 1135 waivers, such authorities included section 1915(c) waivers and 1115 demonstrations.

a. Medicare Section 1135 Waivers and Flexibilities during the COVID-19 PHE

As noted under section II.B, Medicare has three sets of potential temporary adjustments to address an emergency or disaster situation, including:[36]

- Applying flexibilities already available under normal business rules, with flexibilities defined as "changes in policy that CMS makes without invoking section 1135";[37]
- Waiver or modification of policy or procedural norms by the CMS Administrator; and
- Waiver or modification of certain Medicare requirements under section 1135 waiver authority, either as blanket or individual waivers.[38]

Given that COVID-19 has not been geographically bound and has required a consistent response across regions, CMS discontinued processing most Medicare waiver requests on a regional basis and took a national view on waiver request with consideration of local data and input from regions. Other than the COVID-19 Workgroup, CMS relied on clinical expertise from senior CMS clinicians, input from the regional offices and other existing workflows and workgroups to examine issues and formulate recommended actions.

Important steps in the workflow included the following:

1. **Receiving and preparing Section 1135 waivers.** CMS reviewed the model waiver list typically considered in advance of an emergency with the first requests for waivers. The lists covered Medicare Fee-for-Service (FFS) policies, appeals, provider enrollment, and conditions of participation and were based largely on CMS responses to prior smaller-scale emergencies. CMS followed established standard operating procedures (SOPs) to collect information and technical direction from within CMS and then refined the model waiver list to address the COVID-19 PHE. CMS also attempted to proactively identify needs prior to requests to stand ready to address evolving needs. CMS also improved upon its intake process by developing a more efficient Automated Medicare section 1135 Request Form with video and written instructions[39]. This system can rapidly produce utilization and status reports to aid in tracking of requested waivers.

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[35] See Appendix H for more detailed information about CMS internal triage related to management of Medicare-related waiver requests.

[36] CMS, "Medicare Fee-For-Service. Emergency-Related Policies and Procedures That May Be Implemented Without Section 1135 Waivers," August 11, 2023, Question B-1.

[37] CMS, "Medicare Fee-For-Service Emergency and Disaster Frequently Asked Questions (FAQs) Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only With a Section 1135 Waiver," August 1, 2023.

[38] United States Government Accountability Office (GAO), "Medicare and Medicaid COVID-19 Program Flexibilities and Considerations for Their Continuation," May 19, 2021: 4-5.

[39] Centers for Medicare & Medicaid services. Automated Medicare section 1135 Request Form. Accessed September 17, 2024.

2. **Drafting additional waivers as needed.** As the pandemic progressed and additional needs were identified, CMS drafted additional section 1135 waivers specific to the COVID-19 PHE. The additional waivers were to address emerging or anticipated needs not covered by the model waiver list of emergency response waivers and flexibilities.
3. **Reviewing and deciding on the status of waivers.** The centers shared the compiled list of section 1135 blanket waivers (including model waiver list waivers and those specific to COVID-19) with the Rapid Response Waiver workgroup and a group of senior CMS clinicians as a first line of review and discussion. The next step was presentation of the waivers to the COVID-19 Workgroup, with attendance by the CMS Administrator to expedite decision making. The Workgroup considered how waiver proposals from one center related to other programs, for example, evaluating opportunities for a consistent, enterprise-wide approach to policy changes for Medicare, Medicaid, CHIP, and the Marketplace. Where possible, the Workgroup considered the impact of proposed waivers on underserved populations and on program integrity.
4. **Clearance of waivers and related policy guidance.** If approved, waivers were placed into final format and sent to HHS for clearance. Policy guidance went through an expedited clearance process to facilitate formal policy adjudication.
5. **Releasing waivers to the public.** Approved waivers and flexibilities were posted to CMS' Emergency Preparedness and Response Operations (EPRO) website on the CMS Current Emergencies page. Waivers and flexibilities were communicated to CMS field staff working directly with interested parties to ensure that all CMS staff received timely notice of policy changes. Section 2 below provides more details on the CMS outreach and engagement efforts.
6. **Providing waiver-related guidance**. Center representatives issued Technical Direction Letters as needed, advising the Medicare Administrative Contractors (MACs) of the declared PHE, and the MACs provided direction on waiver implementation in the affected areas. CMS also provided guidance through fact sheets and Quality Safety and Oversight (QSO) memos.

Following the general process described above, the CMS Waiver Request Team identified, organized, sorted, and categorized waiver requests, with most requests determined to be covered under blanket waivers. Exhibit 4 specifies the five categories assigned to describe the status of section 1135 Medicare waiver requests (that is, covered by blanket waiver, approved, denied, resolved under current law, or withdrawn); the total number of waiver requests processed; and the percentage by status type.

Exhibit 4: Section 1135 Medicare Waivers Processed by Status, Number, and Percentage

Status	Number of Waivers Processed	Percentage by Status Type
Covered Under Blanket Waiver	233,178	85.20
Approved	325	0.118
Denied	33,037	12.07
Already permitted under current regulations	497	0.182
Withdrawn	6,641	2.42
Total	273,678	100

CMS also denied requests to waive regulations that the agency determined were critical to patient safety. This included requests to waive requirements that facilities test fire extinguishers, motor-driven fire pumps, and emergency generators; and that facilities perform scheduled maintenance for infection control utility systems. Other 1135 waiver requests which CMS denied included requests to waive hospitals' Accrediting Organization surveys; multiple requests for exemptions from requirements that facilities require staff to be

administered the COVID-19 vaccine; modification of Medicaid HCBS adult training programs and requirements for active treatment; and the LTC facility requirement at 42 CFR § 483.35(b) that a registered nurse be present in a long-term care facility at least eight hours a day, seven days a week and for a registered nurse to serve as a director of nursing.[40]

b. Medicaid and CHIP Section 1135 Waivers and Flexibilities under COVID-19

Within days of the COVID-19 PHE declaration, CMCS released a suite of tools for states that streamlined waiver requests and expedited federal approval of state Medicaid and CHIP changes to respond to the PHE. In March 2020, CMS released a revised Medicaid Disaster Response Toolkit (originally launched in August 2018) and issued four templates to support states in the process of applying for federal waivers or identifying other relevant authorities to implement program flexibilities more efficiently.[41]

The template enabled states to readily choose section 1135 flexibilities needed for the COVID-19 PHE (if applicable). In addition to standard waiver requests, many states used the "other" section of the template to describe additional requests not previously approved for natural disasters and PHEs. CMCS developed a process to review and adjudicate these requests, which were submitted via email. During the COVID-19 PHE, CMCS approved state-specific waivers to address the needs of Medicaid and CHIP beneficiaries and to ensure access and timely payment to health care providers (see Appendix F).[42]

As was the case for Medicare, CMCS had never experienced such a large volume or variety of section 1135 waiver requests and other requests for policy modifications. CMCS worked quickly to identify staff resources and to develop new processes for reviewing waiver requests, starting with a small response team to review and adjudicate section 1135 state submissions as quickly as possible. The CMCS section 1135 Response Team was tasked with reviewing state submissions and preparing standard waiver approval letters to be issued by the Office of the Center Director within three business days.

This Response Team quickly developed an internal review protocol, including a peer review process, to ensure consistent review and efficient processing of waiver requests. In addition, the CMCS 1135 Response Team held daily calls to discuss incoming requests, assign reviewers, determine target approval dates, and develop an approval letter template and assessment table for reviewers to document all state requests. When non-standard requests were determined appropriate to consider under section 1135 waiver authority, the team consulted with subject matter experts (SMEs) and the Office of the General Counsel to develop waiver language and to ensure the new waiver type could be approved under section 1135 authority.

Because CMCS established a "no wrong door" policy, many requests submitted using the template were not appropriate to consider under section 1135. For this reason, the CMCS 1135 Waiver Response Team coordinated with another new team, the CMCS Triage Team, comprising a cross-section of CMCS SMEs. The Triage Team reviewed the assessment tables (as noted earlier, for documenting state requests) where response team members noted whether requested PHE-related flexibilities:

- Could be approved under section 1135 authority.
- Might require further review and/or consideration under a different authority—for example, a Medicaid State Plan amendment or section 1115 demonstration—and/or concurrence process.
- May be addressed in guidance documents, for example, a frequently asked question (FAQ).

The Triage Team convened regular meetings to confirm or identify the authority under which various state requests could be approved, to establish the primary point of contact for each request, and to confirm next steps.

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[40] 42 CFR. § 483.35(b)

[41] CMS, "RE: Planning for the Resumption of Normal State Medicaid, Children's Health Insurance Program (CHIP), and Basic Health Program (BHP) Operations Upon Conclusion of the COVID-19 Public Health Emergency," December 22, 2020.

[42] CMS, "Federal Disaster Resources," Medicaid.gov, accessed January 10, 2024.

Home and community-based services (HCBS) was a key area for state-specific action during the PHE. CMCS worked closely with states to approve section 1135 waivers for HCBS and/or Appendix K amendments to section 1915(c) HCBS waiver programs so states could more flexibly address COVID-19 for HCBS recipients under their Medicaid programs.[39] Many flexibilities for Medicaid HCBS programs were provided through section 1915(c) Appendix K amendments and some states used section 1115(a) demonstrations to authorize HCBS-like flexibilities under the section 1115 demonstration programs. Under these authorities, states had the option to modify or expand eligibility criteria for coverage of HCBS, modify or suspend service planning and delivery requirements, use telehealth or other electronic methods for delivery of some service, or adopt policies to support providers, e.g., modify provider qualifications. CMCS posted a sample Appendix K template[43] for COVID-19 amendment requests for section 1915(c) HCBS waiver programs and provided updated guidance[44] in December 2020, noting that, at the state's discretion, emergency provisions under Appendix K could be extended for up to six months after the end of the COVID-19 PHE.

CMCS consulted with Medicare, the Center for Clinical Standards and Quality (CCSQ), and the Center for Program Integrity (CPI) to determine whether state requests submitted using the Medicaid and CHIP template could be covered under blanket waivers or other guidance. Some requests submitted to Medicaid were sent to CCSQ for processing or were withdrawn if the flexibilities had already been granted under Medicare.

CMCS also amended federal Medicaid regulations concerning home health and testing services. The first change to Medicaid home health regulations at 42 CFR. § 440.70 was effective on March 1, 2020. This change allowed other licensed practitioners to order home health services, for the period of the PHE for the COVID–19 pandemic in accordance with state scope of practice laws. The second change to the home health regulations allowed states to include physician assistants, nurse practitioners, and clinical nurse specialists as individuals who could order home health services. These changes were permanent and applicable to services provided on or after March 1, 2020.

CMCS amended the regulation implementing the "other laboratory and X-ray services" benefit at 42 CFR. § 440.30. This change provided states with the flexibility to cover certain laboratory tests and X-ray services that may not meet certain requirements in § 440.30(a) or (b) (such as the requirement that tests be ordered and provided by a physician or other licensed practitioner in an office or similar facility). This flexibility was retroactive to March 1, 2020, during the period of the COVID–19 PHE, and also applies during future PHEs resulting from outbreaks of communicable disease and subsequent periods of active surveillance. This flexibility was needed to allow coverage for COVID-19 testing in non-office locations, coverage for laboratory processing of self-collected laboratory test systems that the FDA authorized for home use (in certain circumstances), and to cover COVID-19 tests without an order. Of note, this regulatory amendment took effect prior to certain changes Congress eventually made to the Medicaid statute - most notably, section 9811(a) of the American Rescue Plan Act (ARPA) added a new section 1905(a)(4)(F) to mandate coverage of COVID-19 tests for the period beginning on March 11, 2021 and ending on September 30, 2024 (the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act). Section 9821 of the ARPA amended the CHIP statute to include a similar temporary benefit in CHIP.

[43] Ibid.

[44] CMCS, "State Health Official Letter #20-004, RE: Planning for the Resumption of Normal State Medicaid, Children's Health Insurance Program (CHIP), and Basic Health Program (BHP) Operations Upon Conclusion of the COVID-19 Public Health Emergency," December 22, 2020.

2. CMS' Approach to Communication of Section 1135 Waiver Activities

CMS' Office of Communications, regional offices, Senior Clinicians and centers sponsored hundreds of Medicare "Office Hours", State Medicaid Director calls, stakeholder calls, and regional offices sessions that were often attended by several thousand external interested parties. These calls and the other tools mentioned below were important in communicating the availability of waivers and answering questions on their use.

- CMS immediately revamped the CMS.gov webpage to prominently display an icon that directed interested parties to the site with COVID-19 emergency information. The site catalogued information so that users could more easily find the waivers and flexibilities in their area of interest including information for multiple provider type, laboratories, telehealth, billing and coding, provider enrollment, survey and certification and other types of guidance.
- CMS offered a forum for sharing best practices through provider calls and held office hours to address FAQs or concerns. CMS sought to provide frequent updates and information regarding waivers or modifications that changed existing Medicare, Medicaid, CHIP and Marketplace requirements and to gather information from external interested parties to improve processes and meet needs efficiently.
- CMS hosted frequent COVID-19 calls in collaboration with other federal agencies such as the CDC, HRSA, and FDA to provide coordinated information to interested parties, including state and local governments, nursing homes, home health providers, and hospice providers. CMS also participated in external engagement sessions with HHS and the Executive Office of the President to ensure consistency in communications.
- CMS provided an opportunity for live dialogue between CMS and external interested parties through regularly scheduled Open Door Forums. The forums aimed to foster strong collaboration and communication between CMS and diverse communities of interest and were held frequently during the PHE to share information about waivers and flexibilities, among other policies and initiatives.
- CMS regularly published and updated resources to support external interested parties in understanding and applying waivers and flexibilities. For example, a set of COVID-19 FAQs were an important resource to clarify Medicare policy changes. Moreover, provider-specific fact sheets included updates on the status of CMS waivers and flexibilities (whether terminated, made permanent, or ended with the end of the PHE). CMS also published 52 Quality and Safety Oversight memos which served to clarify or remind state and federal surveyors and the healthcare provider community about existing policies. These memos were also used to share best practices.
- CMS routinely published extensive guidance through state Medicaid director letters, state health official letters, and informational bulletins. Other resources have included toolkits and checklists to ensure states had current information.
- CMS hosted All-State calls with state Medicaid agencies and other external partners beginning in March 2020; the calls continue to be widely attended. CMS continues to meet weekly with the National Association of Medicaid Directors (NAMD) to support state unwinding efforts. "Unwinding" is the term for states' resumption of annual Medicaid eligibility reviews after the end of the continuous enrollment condition in section 6008(b)(3) of the Families First Coronavirus Response Act.
- CMS also had a very comprehensive approach to beneficiary outreach and engagement to ensure that they were kept informed during the COVID-19 PHE. For example, CMS dedicated a section of the Medicare.gov website to Medicare Coronavirus Information that explained what would still be covered at the end of the PHE and how to get vaccines. The extensive beneficiary outreach efforts are not included in this report since they were not the direct recipients of section 1135 waiver and flexibility information; however, they were at the center of all decisions made during this time period and thus worthy of mention in this section.

3. CMS Approach to Key Areas of Section 1135 Waivers and Flexibilities

CMS addressed several priority areas through section 1135 waivers and other flexibilities. This report focuses on six key areas that provide insight into the approach used to accomplish the purpose of the section 1135 waivers. The six key areas include waivers and flexibilities for: 1) vaccines and therapeutics; 2) testing; 3) telehealth; 4) emergency reporting; 5) surge capacity; and 6) LTC. For each key area, we describe the actions taken by Medicare and Medicaid, including regulations, sub-regulatory actions, and waivers. In some cases, section 1135 waivers were used extensively, while for others, such waivers were not used; for example, CMCS also used other authorities such as section 1915(b), 1915(c), and 1115 waivers.

a. Vaccines and Therapeutics

CMS took regulatory and sub-regulatory action regarding vaccines and therapeutics, advancing a multi-pronged, government-wide strategy to protect against COVID-19 surges. CMS also responded to challenges related to payment for and underutilization of vaccines and therapeutics.

Establishing coding and payment rates. Vaccines for COVID-19 did not exist before the PHE. During the PHE, the new COVID-19 vaccines were covered under Medicare Part B pursuant to section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, Pub. L. 116-136) under the same authority as other preventive vaccines. CMS implemented regulations to ensure that providers and suppliers would be paid for administering COVID-19 vaccines under Medicare as soon as the FDA authorized or approved the product through an emergency use authorization (EUA) or biologics license application, respectively.[45] In addition, under Medicaid, some states used SPAs to temporarily increase the payment for COVID-19 vaccine administration to 100 percent of the Medicare rate.[46] Section 9811 of the American Rescue Plan Act of 2021 (ARPA, P.L. 117-2) established mandatory coverage of COVID-19 vaccines and their administration for nearly all Medicaid beneficiaries (both adults and children), without cost sharing, beginning March 11, 2021, and ending on September 30, 2024 (the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act) (the "ARPA coverage period"). States with no state plan coverage of vaccine administration for certain populations were required to submit a state plan amendment to demonstrate compliance with the ARPA coverage requirements.

Expanding access to vaccines and therapeutics. A key part of the emergency response was FDA authorization of the emergency use of monoclonal antibodies and oral antivirals.[47] In response, CMS anticipated the need to broaden the types of products covered under the Part B COVID-19 vaccine benefit for coverage and payment under Medicare Part B, and exercised enforcement discretion regarding which types of entities could bill for vaccine or monoclonal antibody product administration in certain institutional settings. Consequently, in November 2020, CMS issued its first regulations enabling payment for COVID-19 vaccines and therapeutics under Medicare.[48] For Medicaid, ARPA also established mandatory coverage of COVID-19-related treatment during the period from March 11, 2021 through September 30, 2024.[49]

Enhancing safety in health care settings. Vaccines were underutilized among health care workers, particularly those employed in LTC facilities. CMS sought to promote vaccination through new regulations

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[45] CMS, "Fourth COVID-19 Interim Final Rule with Comment Period (IFC-4)," October 28, 2020.
[46] CMS, "Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost-Sharing Under Medicaid, the Children's Health Insurance Program, and Basic Health Program," May 6, 2022.
[47] CMS, "Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19," November 6, 2023.
[48] "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-9912-IFC, published November 6, 2020).
[49] CMS, State Health Official Letter #21-006, "RE: Mandatory Medicaid and CHIP Coverage of COVID-19-Related Treatment under the American Rescue Plan Act of 2021" (October 22, 2021), https://www.medicaid.gov/federal-policy-guidance/downloads/sho102221.pdf.

and sub-regulatory guidance, requiring such facilities to educate staff and residents about the benefits of vaccines and establishing vaccination requirements for health care workers as a condition of participation.[50]

b. COVID-19 Testing

CMS streamlined the processes for clinical laboratories and health care providers to fulfill diagnostic testing for COVID-19. Actions included enhancing accessibility, regulating payments, and establishing standards for CLIA-certified laboratories.

Increasing access through Medicaid. CMS depended on new legislation to provide resources or new authorities where 1135 waiver authority was not sufficient. For example, the Families First Coronavirus Response Act (FFCRA, P.L. 116-127), the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116-136), and the American Rescue Plan Act of 2021 (ARPA, P.L. 117-2), amended the Medicaid statute to authorize an optional Medicaid eligibility group for uninsured individuals for whom states could cover COVID-19 testing and testing-related services, COVID-19 vaccines and their administration, and COVID-19-related treatment with 100 percent federal matching funds. Separately, CMS modified the Medicaid laboratory and X-ray services benefit regulation to allow coverage of such services that may not have met certain requirements in § 440.30(a) or (b), such as furnishing tests in non-office locations, under certain circumstances during a PHE.[51] After the ARPA amended the Medicaid and CHIP statutes to include the temporary mandatory COVID-19 testing coverage referenced above, CMS also issued guidance regarding coverage and payment of COVID-19 testing in Medicaid and CHIP, emphasizing that the ARPA-mandated coverage included all FDA-authorized COVID-19 tests, including point-of-care and home tests.[52]

Enhancing and regulating Medicare payments. Throughout the PHE, new Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT®) codes for COVID-19 diagnostic testing were developed. Initially, CMS used its established Medicare policies whereby the Medicare Administrative Contractors (MACs) set initial payment amounts for COVID-19 tests, and later issued a CMS Ruling to establish payment amounts for certain COVID-19 tests performed on high-throughput platforms.[53] In addition, CMS used regulations to establish increased payments for specimen collection under certain circumstances.[54] As COVID-19 testing became more readily available, CMS addressed overutilization of tests, issuing regulations to clarify ordering requirements.[55] Further, CMS updated payments for high-throughput COVID-19 tests through a second CMS Ruling, ensuring Medicare payment reflected the resources necessary for accurate and rapid processing of a large volume of tests performed on advanced technology.[56]

Establishing testing standards and requirements. During the PHE, CMS' review and processing of Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate applications was expedited to ensure that laboratories in the US could quickly begin COVID-19 testing. In addition, CMS required CLIA-

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[50] "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination" (CMS-3415-IFC, published November 5, 2021)

[51] "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (CMS-5531-IFC, published May 8, 2020).

[52] CMS, State Health Official Letter #21-003, "RE: Medicaid and CHIP Coverage and Reimbursement of COVID-19 Testing under the American Rescue Plan Act of 2021 and Medicaid Coverage of Habilitation Services" (August 30, 2021), https://www.medicaid.gov/federal-policy-guidance/downloads/sho-21-003.pdf.

[53] CMS, "Ruling No.: [CMS-2020-01-R]" CMS-1682-R Signed Version (Accessed October 23, 2024)

[54] CMS, "Medicare COVID-19 PHE Waivers and Flexibilities (active)," Accessed January 10, 2024.

[55] CMS, "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID– 19 Public Health Emergency" September 2, 2020.

[56] CMS, "Ruling No.: CMS-2020-1-R2" cms-ruling-2020-1-r2.pdf (Accessed October 23, 2024).

certified laboratories to report COVID-19 test results to the Secretary of HHS during the duration of the PHE.[57] CMS does not have section 1135 waiver authority to grant waivers or exceptions that are not established in statute or regulation. In addition, the section 1135 waiver authority is only applicable to specific programs (or penalties) authorized by the Social Security Act, and CLIA is not among these programs. Therefore, CMS relied on its existing authorities and the regulatory process to provide certain flexibilities related to CLIA-certified laboratories during the COVID-19 PHE.

c. Telehealth

During the COVID-19 PHE, relying on a combination of emergency rulemaking and new statutory authority, CMS issued section 1135 waivers and regulatory changes for Medicare to expand access to services delivered using telehealth, broadening the scope of services that could be provided via telehealth and the types of clinicians that can provide services via telehealth. In addition, CMS issued section 1135 waivers and other flexibilities that allowed states to expand access to certain Medicaid services delivered using telehealth, and many states used these flexibilities to expand telehealth for their programs.

Eliminating provider and beneficiary restrictions. CMS used section 1135 authority, including new statutory language specific to Medicare telehealth added during the PHE, to waive Medicare requirements specifying the types of clinicians that can provide telehealth, extending to all Medicare-enrolled clinicians.[58] CMS also waived telehealth restrictions related to the geographic location of Medicare-enrolled clinicians and beneficiaries.[59,60] Before the COVID-19 PHE, with a few exceptions, payment for Medicare telehealth services was limited to services provided beneficiaries in rural areas. In most instances, Medicare beneficiaries could not receive services delivered using telehealth in their homes. CMS waived these requirements during the COVID-19 PHE, granting Medicare beneficiaries broad access to telehealth services, including in their homes, without geographic or location limits. CMS also implemented new statutory telehealth flexibilities for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs), home health agencies, hospices, and Medicare Advantage (MA) organizations.[61]

State Medicaid agencies generally have the flexibility to determine which Medicaid providers can deliver services using telehealth. During the PHE, states could use the Medicaid Disaster Relief SPA template to temporarily add provider types authorized to deliver services using telehealth.

Expanding eligible services and modalities. During the PHE, there was a significant expansion of the types of Medicare services that could be furnished via telehealth and some Medicare services could be delivered via the audio-only modality.[56] CMS waived requirements that certain Medicare visit types be conducted in person, allowing telehealth visits as appropriate, and limitations on visit frequency for certain Medicare services delivered via telehealth. In addition, clinicians could provide Medicare e-visits and remote physiological monitoring services to new patients—services previously restricted to established patients.

An ASPE analysis found that about one quarter of all Medicare telehealth visits in both 2020 and 2021 were conducted through the audio-only modality. The report also spotlighted a surge in audio-only eligible telehealth visits—from less than 200,000 visits in 2019 to 18 million visits in 2020 and 14 million visits in 2021. This substantial growth underscored the pivotal role the audio-only modality played in expanding access to telehealth during the PHE.[62]

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[57] CMS, "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-3401-IFC, published September 2, 2020).
[58] CMS, "Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19," November 6, 2023.
[59] CMS, "Medicare COVID-19 PHE Waivers and Flexibilities (active)," Accessed January 10, 2024.
[60] CMS, "Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19," November 6, 2023.
[61] CMS, "Medicare COVID-19 PHE Waivers and Flexibilities (active)," Accessed January 10, 2024.
[62] ASPE, Updated Medicare FFE Telehealth Trends by Beneficiary Characteristics, Visit Specialty and State, 2019-2021, July 20, 2023.

For Medicaid, during the PHE, CMS allowed states to use section 1135 waivers to waive certain regulatory requirements that would otherwise restrict use of telehealth for certain benefits or certain service assessments or screenings. For example, states could use a section 1135 waiver to permit states to cover clinic services furnished via telehealth when neither the patient nor the clinic practitioner was physically onsite at the clinic. Additionally, if a Medicaid state plan contained restrictions that would prevent an otherwise covered service from being provided via telehealth or via a certain telehealth modality,[63] states could use the Medicaid Disaster Relief SPA template to temporarily remove such restrictions during the period of the PHE.

Modifying telehealth payments. Recognizing that telehealth services were broadly substituted for in-person services during the PHE, CMS permitted clinicians billing Medicare for telehealth services to report the place of service code that would have been used had the service been furnished in person.[64] This change ensured that clinicians would be paid the same rate for providing a service via telehealth as providing the service in person. Under this policy, a practitioner who typically sees patients in an outpatient provider-based clinic of a hospital would be paid the facility rate for telehealth services; comparatively, a practitioner in an office setting would be paid at the non-facility, or office, rate for such telehealth services. In addition, the Office of Inspector General (OIG) notified clinicians that they would not be subject to administrative sanctions under certain fraud and abuse authorities if the clinicians waived or reduced cost-sharing obligations for telehealth services furnished consistent with then-applicable payment and coverage rules.

Generally, state Medicaid agencies have the flexibility to establish payment rates for Medicaid services delivered using telehealth, and CMS allowed states to use the Medicaid Disaster Relief SPA template to temporarily increase payments to Medicaid providers during the PHE. This included, but was not limited to: increasing payments to providers that were seeing an influx in Medicaid patients as a result of the PHE; recognizing additional costs incurred through the provision of Medicaid services to COVID-19 patients; increasing payments to recognize additional cost incurred in delivering Medicaid services, including additional staff costs and/or personal protective equipment; adjusting payments to providers to account for decreases in service utilization but an increase in cost per unit due to allocation of fixed costs or an increase in patient acuity as a result of the PHE; or increasing payments for Medicaid services delivered via telehealth to ensure that Medicaid services were delivered in a safe and economical manner.

Expanding state Medicaid flexibilities for telehealth. States generally have flexibility in designing the parameters of service delivery using telehealth in Medicaid and CHIP.[65] This broad flexibility to cover and pay for services delivered via telehealth was in place prior to the COVID-19 PHE and continues to be available to states. Such flexibilities include the option to determine-what types of covered services may be delivered via telehealth; what types of providers may deliver services via telehealth; and what payment parameters will support telehealth. During the COVID-19 PHE all states, the District of Columbia, and three territories expanded the types of telehealth modalities that could be used to deliver covered Medicaid services, and many states added or expanded service delivery via audio-only telehealth.[66] Similarly, many states considered authorizing additional services for delivery via telehealth and paid additional provider types for services delivered via telehealth, relaxed originating site rules, and implemented coverage and payment parity to pay for services delivered via telehealth the same way they were covered and paid for when delivered in person.

D. Emergency Reporting

CMS recognized the need to ease the administrative burden of certain reporting requirements to enable providers to focus on patient care during the COVID-19 PHE. As a result, cost and quality reporting requirements were relaxed. At the same time, CMS played a critical role in collecting valuable information

[63] CMS, "State Medicaid & CHIP Telehealth Toolkit," Accessed January 10, 2024.
[64] CMS, "Medicare COVID-19 PHE Waivers and Flexibilities (active)," Accessed January 10, 2024.
[65] CMS, "State Medicaid & CHIP Telehealth Toolkit," Accessed January 10, 2024.
[66] Ibid.

needed to manage the PHE. As a result, CMS issued regulations requiring providers to report key data related to COVID-19.

Relaxing reporting requirements. CMS used both regulations and sub-regulatory guidance to grant extensions and exceptions for quality reporting requirements, including the Merit-based Incentive Payment System (MIPS) and the Medicare Shared Savings Program (Shared Savings Program), as well as hospital and post-acute care quality reporting programs.[67] For example, CMS made reporting optional for the first half of 2020 for the Home Health, Hospice, Inpatient Rehabilitation, Long-Term Care Hospital, and Skilled Nursing Quality Reporting Programs.[68] Many providers continued to report if they were able to. This flexibility helped to relieve provider reporting burden during the time of an emergency and acknowledged that the data would not necessarily be reflective of routine care processes generally measured by quality data. At the same time, CMS did note many indicators that health care safety and quality declined. The PHE disrupted many normal activities in hospitals and other facilities. The fact that the pandemic degraded patient safety so quickly suggests that the health care system lacks a sufficiently resilient safety culture and infrastructure.

Requiring COVID-19 data reporting. CMS used both regulatory and sub-regulatory guidance to increase reporting requirements for epidemiological information, to gather critical data on the spread of COVID-19 and related deaths.[69,70] For example, this included reporting new positive cases to both local and state health agencies as well as reporting to the CDC's National Healthcare Safety Network system. Reporting was especially important for hospitals, LTC facilities, and laboratories. CMS provided notification when reporting was lacking and then enforced through civil monetary penalties or termination for non-compliance.[71]

e. Surge Capacity

The COVID-19 PHE led to rapid increases in caseloads at hospitals, many of which did not have adequate beds or staff to respond. CMS issued section 1135 waivers and regulations to support hospitals as they increased capacity due to the COVID-19 PHE, specifically by expanding permissible capacity within their own facilities, allowing hospitals to provide services in alternative non-hospital care settings, and waiving sanctions for certain violations of the physician self-referral law.

Expanding physical capacity. To allow for increased capacity and facilitate appropriate grouping of COVID-19 patients, CMS waived certain physical environment requirements under the Medicare conditions of participation for various inpatient facilities, to increase flexibilities for surge capacity and patient quarantine at acute care hospitals, psychiatric hospitals, and critical access hospitals (CAHs).[72] CMS temporarily permitted facility and non-facility space not normally used for patient care to be used for patient care or quarantine.

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[67] CMS, "Medicare COVID-19 PHE Waivers and Flexibilities (active)," Accessed January 10, 2024.
[68] CMS, Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Report, May 8, 2020.
[69] CMS, Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, September 2, 2020.
[70] CMS, Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Report, May 8, 2020.
[71] "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-3401-IFC, published September 2, 2020).
[72] Ibid.

To allow CAHs flexibility in establishing surge site locations, CMS instituted flexibilities regarding the Medicare requirements for CAHs regarding rural location and distances to other hospitals or CAHs.[73] CMS also waived CAH off-campus and co-location requirements, giving flexibility for CAHs to establish temporary off-site locations. In addition, to further increase CAH capacity to care for the COVID-19 patients, CMS waived requirements limiting CAH beds to 25 and the length of stay to 96 hours.

Alternatives to the hospital setting. In addition to flexibilities allowing hospitals to treat more patients in an inpatient setting, CMS issued waivers and subregulatory guidance to facilitate Medicare beneficiary treatment in alternative settings, to help alleviate overcrowded hospitals and to reduce COVID-19 transmission in hospitals. These included:

- **SNF 3-day Rule Waiver.** As noted earlier, under the COVID-19 PHE, CMS effectively waived the requirement that Medicare-covered SNF stays be preceded by a 3-day qualifying inpatient hospital stay.[74] By activating statutory authority that permitted coverage without a three-day hospital, this coverage allowed hospitalized patients to be transferred to SNFs more quickly, making more inpatient beds available.
- **Hospital Without Walls.** To expand care capacity and develop sites dedicated to treating COVID-19 patients, CMS' Hospital Without Walls waivers provided broad regulatory flexibility for hospitals to provide patient services outside of existing locations.[75] Under the new guidance, hospitals could still receive Medicare payments for patients transferred to outside facilities, such as ambulatory surgical centers (ASCs), inpatient rehabilitation facilities (IRFs), and even hotels and dormitories. The ASCs could contract with local health care systems to provide hospital services or be temporarily certified as hospitals. [76]
- **Acute Hospital Care at Home.** The Acute Hospital Care at Home (AHCAH) initiative expanded on the Hospital Without Walls program, giving participating hospitals the flexibility to treat eligible Medicare beneficiaries—who would otherwise require an inpatient admission—in their homes.[77] The initiative aimed to make more inpatient hospital beds available to accommodate surges in COVID-19 patients, as well as to limit the exposure of at-risk patients to the virus. As of February 4, 2024, CMS had approved AHCAH applications for 313 hospitals across 131 systems, in 37 states.[78] The Consolidated Appropriations Act, 2023 extended the waivers and flexibilities associated with the ACHAH initiative until December 31, 2024, established explicit criteria that hospitals must meet to participate in the initiative, and required a separate report to Congress, which is currently in progress. Additional details regarding the ACHAH initiative will be provided in that report.

f. Long-Term Care Facilities

For LTC facilities, reducing the transmission of COVID-19 has been a top priority since the emergence of the pandemic.[79] In 2020, LTC facility residents were 14 times more likely to be diagnosed with COVID-19

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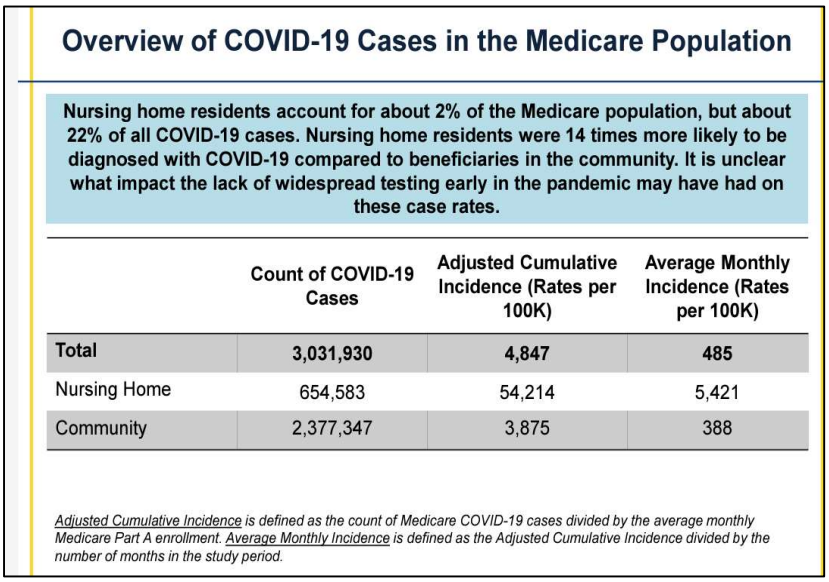
[73] Ibid.
[74] CMS, "Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19," May 10, 2023.
[75] CMS, "Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge Fact Sheet," March 30, 2020.
[76] CMS, "Guidance for Processing Attestation Statements from Ambulatory Surgical Centers (ASCs) Temporarily Enrolling as Hospitals during the COVID-19 Public Health Emergency ***REVISED***" QSO-20-24-ASC-Revised, November 25, 2020.
[77] CMS, "CMS Announces Comprehensive Strategy to Enhance Hospital Capacity Amid COVID-19 Surge," press release, November 25, 2020.
[78] "Acute Hospital Care at Home Resources," qualitynet.cms.gov, accessed January 18, 2024.
[79] LTC facilities include skilled nursing facilities (SNFs) and nursing facilities (NFs). CMS, "State Operations Manual Appendix PP - Guidance to Surveyors for Long Term Care Facilities," Accessed January 10, 2024.

than beneficiaries in the community.[80] While LTC facility residents account for about 2 percent of the Medicare population, in 2020 they comprised about 22 percent of all COVID-19 cases.[81]



Overview of COVID-19 Cases in the Medicare Population

Nursing home residents account for about 2% of the Medicare population, but about 22% of all COVID-19 cases. Nursing home residents were 14 times more likely to be diagnosed with COVID-19 compared to beneficiaries in the community. It is unclear what impact the lack of widespread testing early in the pandemic may have had on these case rates.

	Count of COVID-19 Cases	Adjusted Cumulative Incidence (Rates per 100K)	Average Monthly Incidence (Rates per 100K)
Total	**3,031,930**	**4,847**	**485**
Nursing Home	654,583	54,214	5,421
Community	2,377,347	3,875	388

Adjusted Cumulative Incidence is defined as the count of Medicare COVID-19 cases divided by the average monthly Medicare Part A enrollment. Average Monthly Incidence is defined as the Adjusted Cumulative Incidence divided by the number of months in the study period.

Medicare-covid-19-nursing-home-analysis

Expanding physical capacity. CMS issued Medicare waivers to increase the physical capacity of LTC facilities to isolate residents.[82] Non-SNF/NF buildings were enabled to be temporarily certified as SNFs, and CMS waived certain certification requirements for opening a nursing facility. Further, CMS allowed for LTC facility rooms not traditionally used as resident rooms (e.g., activity rooms, conference rooms) to be used to house residents in emergency and surge situations.

In addition, Under Medicaid, CMS authorized states to allow facilities to be fully reimbursed by Medicaid for services rendered in an unlicensed facility during an emergency evacuation or if residents had to be relocated, provided that the state made a reasonable assessment that the facility met minimum standards to ensure the health, safety, and comfort of beneficiaries and staff.[83]

Flexibilities were provided to transfer Medicare beneficiaries within and across facilities, to help facilities respond to changing conditions and emergency situations.[84] CMS waived certain requirements to enable facilities to group or quarantine residents with COVID-19 diagnoses or symptoms and to separate them from residents who were COVID-negative and asymptomatic. Quarantine helped prevent the spread of the virus and aimed to ensure that COVID-19 patients resided in locations best suited for treatment. CMS waived certain discharge and transfer Medicare requirements to allow facilities to transfer COVID-19 patients to isolation and treatment facilities and COVID-19 negative patients to separate locations, to prevent spread of the virus.

Increasing workforce capacity. To help alleviate staffing shortages and maximize the use of all personnel, CMS issued Medicare waivers and offered flexibilities around how care was provided.[85] Demonstration of

[80] CMS, "The Impact of COVID-19 on Medicare Beneficiaries in Nursing Homes," accessed January 10, 2024.
[81] Ibid.
[82] CMS, "Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19," May 10, 2023.
[83] CMS, "Medicaid COVID-19 PHE Waivers & Flexibilities – 1135 Medicaid Waivers," Accessed January 10, 2024.
[84] CMS, "Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19," May 10, 2023.
[85] Ibid.

compliance with certain Medicare training and certification requirements were delayed to increase staff available to provide patient care. Physicians were allowed to delegate more tasks to non-physician clinicians, with appropriate physician supervision. CMS did not waive or change the required frequency of physician visits; however, the visits could be completed by a clinician other than a physician (e.g., advanced practice nurse, physician assistant, etc.). These visits could be accomplished via telehealth in an effort to expand capacity. Additionally, CMS made the reporting of quality data optional for the first two quarters of 2020 to alleviate administrative burden on providers. In the FY 2022 Payment rule, CMS finalized a measure suppression policy in the Hospital Readmissions Reduction Program (HRRP), Hospital-Acquired Condition (HAC) Reduction Program, and Hospital Value-Based Purchasing (VBP) Program under which CMS suppressed the use of measure data if the agency determined that circumstances caused by the COVID-19 PHE affected those measures and the resulting quality scores significantly.

Establishing requirements for infection control. LTC facilities saw high COVID-19 rates during the PHE. In response, CMS issued new regulations and used sub-regulatory guidance to establish requirements and guidance for infection control, including infection control guidelines; requirements for long-term care facilities to report new infections, case counts, and vaccination/treatment data; resident and staff education; vaccine access; and staff testing and vaccination requirements. Quality Improvement Organization (QIOs) provided on the ground technical assistance and were instrumental in detecting breakdowns in infection control practices. They offered education and scenario-based training to enhance the skills of the staff.

Expanding HCBS to keep Medicaid beneficiaries in the community. States used section 1135 waivers, SPAs, 1115 demonstrations, and Appendix K amendments to section 1915(c) HCBS waiver programs to maintain beneficiary access to HCBS. Through section 1135 waivers in particular, states expanded the types of individuals who could provide HCBS, e.g. waiving the conflict-of-interest requirements, allowing legally responsible individuals to be paid providers, and modifying provider qualifications, and the settings in which those services could be provided. For example, some states allowed family members to provide HCBS and allowed services traditionally provided in the community to be provided in alternative settings.

4. Key Regulations Adopted and Legislation Enacted

CMS identified a need for rulemaking when requests could not be addressed by waiving or modifying rules under existing waiver authorities. CMS used the rulemaking process to provide flexibilities that could not be waived or modified under existing authorities; to respond to enacted legislation; and to modify existing regulatory requirements.

In many cases, CMS used Interim Final Rules with Comment Periods (IFCs) to adopt the necessary new policies because, in light of the COVID-19 PHE, it determined there was good cause for waiving (1) the usual legal requirements to provide the public with notice and an opportunity to comment on a proposed rule, and (2) the usual delay in the effective date of the rules. One benefit of IFCs was that rules went into effect upon publication. Review at the Office of Management and Budget (OMB) was expedited during the PHE given the critical importance of rulemaking.

From April 2020 through November 2021, CMS issued six key IFCs to modify underlying regulations for Medicare and Medicaid; see Exhibit 1 for a summary of the IFCs.[86]

[86] The Medicare Shared Savings Program (Shared Savings Program) also made regulatory changes in response to the COVID-19 PHE. The flexibilities allowed under the 1135 waivers for telehealth services and the waiving of the 3-day inpatient hospital stay prior to a SNF stay superseded existing Shared Savings Program flexibilities and applied to Accountable Care Organization (ACO) participating providers and affiliated SNFs. However, these waivers did not address SSP-specific payment and enrollment policies. Therefore, the COVID-19 PHE triggered emergency rule making and regulatory changes. For example, the Shared Savings Program's Extreme and Uncontrollable Circumstances Policy for mitigating shared losses, modifying agreement periods, quality reporting and mitigating losses for all ACOs participating in a performance-based risk track. Finally, the Shared Savings Program excluded COVID-19 episodes of care when establishing or adjusting ACO historical benchmarks and calculating performance year expenditures. (See Appendix I.)

Exhibit 1: Interim Final Rules and Key Provisions

Interim Final Rules with Comment Period (IFCs)	Key Provisions At-a-Glance Note: Not all provisions are listed.
"Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-1744-IFC), (85 FR 19230) April 6, 2020	• Expanded Medicare telehealth availability. • Revised payment policies to provide specimen collection fees and travel allowance to independent laboratories for collecting COVID-19 tests from homebound and non-hospital inpatients. • Temporarily expanded ambulance transport destinations covered under Medicare Part B • Expanded the types of licensed practitioners allowed to order Medicaid home health services. • Provided broader flexibilities for hospitals to provide inpatient services, including services outside the hospital.
"Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (CMS-5531-IFC), (85 FR 27550) May 8, 2020	• Increased accessibility of COVID-19 testing • Further expanded Medicare telehealth availability. • Delayed reporting requirements for IRF, LTCH, home health, and SNF Quality Reporting Programs. • Required LTC facilities to report COVID-19 infections to the CDC and to inform residents and families of outbreaks in the facility. • Permanently changed professionals who could order Medicaid home health services.
"Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-3401-IFC), (85 FR 54820) September 2, 2020	• Strengthened CMS enforcement of compliance with COVID-19 testing reporting requirements for LTC facilities and laboratories. • Established testing requirements for LTC facility residents and staff. • Required hospitals and CAHs to report COVID-19 information to the CDC. • Established a requirement for CLIA-certified laboratories to report COVID-19 test results. • Updated extraordinary circumstances exceptions for certain value-based purchasing and quality programs.
"Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-9912-IFC), (85 FR 71142) November 6, 2020	• Required providers of COVID-19 diagnostic tests to post cash prices for the duration of the PHE. • Updated payment policies for new COVID-19 treatments.

Interim Final Rules with Comment Period (IFCs)	Key Provisions At-a-Glance Note: Not all provisions are listed.
	• Issued an updated interpretation of the FFCRA condition under which states must maintain Medicaid beneficiary enrollment to receive a temporary increased Federal Medical Assistance Percentage (FMAP).
"Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients and Staff" (CMS-3414-IFC), (86 FR 26306), May 13, 2021	• Required that COVID-19 vaccines be offered to LTC facility residents, clients of ICFs-IID, and staff. • Required LTC facilities to report COVID-19 vaccination status of residents and staff to the CDC.
"Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination" (CMS-3415-IFC), (86 FR 61555), November 5, 2021	• Established COVID-19 vaccination requirements for staff at Medicare- and Medicaid-certified providers and suppliers.

Rulemaking and section 1135 waivers provided emergency flexibility; however, the unprecedented nature of the COVID-19 PHE motivated legislative action to respond more systematically to significant population health needs. From March through December 2022, six laws were enacted to respond to the COVID-19 PHE; see Appendix G for more information. The first three laws were enacted during March 2020 and addressed Congress's immediate priorities, with health provisions focused on Medicare telehealth, LTC facilities, and COVID-19 testing and vaccinations. The need for flexibilities beyond section 1135 waivers highlights the importance of a coordinated, whole-of-government approach to addressing the pandemic.

Waivers or flexibilities issued under section 1135 were expected to terminate with the end of the PHE. However, certain Medicare flexibilities that did not rely on 1135 waiver authority continued after the PHE, given new legislative authorities or regulatory changes. For example, the CAA, 2023 extended certain Medicare telehealth flexibilities through the end of the PHE or December 31, 2024, whichever is later. Other waivers or flexibilities were made permanent (see Appendix I) at the federal level through statutory and regulatory changes, and some states made permanent changes to their Medicaid and CHIP programs through alternate authorities and SPAs.

B. Evaluation of Approaches Used to Accomplish Section 1135 Purposes

In this section, we present an assessment of CMS' use of section 1135 waivers to respond to the COVID-19 PHE, considering real-time evaluations, external feedback from interested parties and areas of program integrity vulnerability introduced with the expansive use of waivers and flexibilities.

1. CMS Evaluation of Approaches

a. Real-Time Evaluation and Action

Over the COVID-19 PHE, CMS conducted real-time evaluation of waivers and flexibilities, and both added and terminated them as needed.[87,88] CMS monitored policies for impacts on safety and quality, for suspected program integrity concerns, and for impact and barriers within communities including a focus on health equity. CMS used a comprehensive, streamlined approach to evaluate and reestablish certain health and

[87] CMS, "Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19," November 6, 2023.
[88] CMS, "Health Care System Resiliency Fact Sheet," accessed January 10, 2024.

safety standards and other financial and program requirements prior to and at the end of the PHE. CMS considered whether providers needed the same blanket waivers at later points during the PHE as in the early stages of the PHE and added and terminated waivers and flexibilities as needed. For example, in April 2021, one year into the PHE, CMS determined that LTC facilities had developed internal policies or other practices that mitigated the need for certain blanket waivers. In response, CMS ended the following emergency blanket waivers which served to restore the following health and safety standards: 1) for notifying residents before transfer or discharge (42 CFR. § 483.15(c)(4)(ii), or room or roommate change (42 CFR. § 483.10(e)(6)); 2) for certain care planning requirements for residents transferred or discharged for purpose of creating a cohort; and 3) for the timeframe requirements for completing and transmitting resident assessment information (Minimum Data Set [MDS]).[89]

In April 2022, given steadily increasing vaccination rates for LTC residents and staff and overall improvements in LTC facilities' ability to respond to COVID-19 outbreaks,[90] CMS ended certain flexibilities for SNFs/NFs and beneficiaries receiving services in inpatient hospices and intermediate care facilities for people with intellectual disabilities (ICF/IID).[91] Waivers provided LTC facilities with necessary operational flexibility, but CMS was concerned about impacts on residents' health and safety that could result from waiving such regulations for an extended time. Specifically, findings from onsite surveys during the PHE revealed significant concerns with resident care unrelated to infection control (e.g., abuse, weight-loss, depression, pressure ulcers). For example, CMS waiver of training requirements may have meant that nurse aides and feeding assistants did not receive necessary training to identify and prevent resident weight loss.

Similarly, CMS waived requirements for physicians and other practitioners to perform in-person assessments, with implications for accurate assessment of residents' clinical needs and possibly contributing to depression or pressure ulcers. Further, the waiver of certain life safety code requirements meant that facilities may not have undergone inspection of fire prevention systems. CMS' monitoring of flexibilities for those that were no longer needed informed the agency's issuing of updated regulations and program guidance.

There were several limitations related to data that constrained monitoring and evaluation of policy changes, specifically related to whether waivers and other flexibilities had the intended effects and whether they were still needed. First, there was little data on blanket waivers because providers did not need to apply for or indicate that they were using a blanket waiver; as a result, CMS did not have a full picture of how policy modifications were used in the field. Second, traditional analyses compare trends to a baseline when analyzing the policy impacts on utilization of care under individual waivers.

During the COVID-19 PHE, there was neither a baseline against which to compare unprecedented utilization patterns (e.g., possible reductions in primary care visits) related to exposure risks or a baseline for new services to meet emerging needs (e.g., over-the-counter COVID-19 tests). Third, when CMS attempted to obtain new data to guide policy implementation efforts (e.g., Federal Coordinated Health Care Office's efforts to collaborate with states to gather data on vaccine uptake), some of their efforts were met with challenges around legal authorities for data collection and timeliness.

b. Evaluation Considerations for Ending the PHE

At the end of the PHE, CMS prioritized ensuring an orderly transition that minimized beneficiary burden and ensured that providers had adequate notice and direction before changes took place. CMS evaluated each of the waivers and flexibilities and released several documents that identified which waivers and flexibilities

[89] CMS, "Updates to Long-Term Care (LTC) Emergency Regulatory Waivers issued in response to COVID-19," April 8, 2021.
[90] CMS, "CMS Returning to Certain Pre-COVID-19 Policies in Long-term Care and Other Facilities," press release, April 7, 2022.
[91] Ibid.

would end with the end of the PHE and which would extend beyond the PHE if possible. A summary of this information was provided on the CMS website and through the Guidance for the Expiration of the COVID-19 Public Health Emergency Quality Safety and Oversight Memo.

CMS also prioritized ensuring an orderly transition for Medicaid and CHIP to routine operations. In anticipation of the end of the PHE, CMS held calls with Medicaid agency leaders in each state, the District of Columbia, and U.S. territories to discuss their plans to return to routine operations at the end of the PHE and to identify technical assistance needs and best practices to share with other states. CMS then provided ongoing targeted technical assistance and monitoring to ensure states were prepared to resume routine operations after the end of the PHE. For example, CMS recommended that states review each provision of their approved temporary SPAs to evaluate, where permissible, whether they wanted to let the provision expire, temporarily extend the provision, or continue an indefinite change through a non-disaster amendment to their state plan. CMS worked with states to determine permissible amendments to their approved section 1915(c) HCBS waivers to incorporate approved Appendix K flexibilities that states determined necessary to continue indefinitely. CMS also worked with states to ensure providers and beneficiaries received adequate notice and time to prepare for changes. See Appendix K of this report for more information about the post-PHE transition process for section 1135 waiver authorities and related flexibilities for Medicaid and CHIP.

After thorough evaluation and discussion, CMS communicated the actions below (Exhibit 3) related to changes in Medicare and Medicaid coverage for vaccines, testing, and therapeutics, and for telehealth post-PHE. A more detailed listing of the disposition of key flexibilities can be found in Appendices B-E.

Exhibit 3: Medicare and Medicaid Coverage Post-PHE

	Medicare	**Medicaid**
Vaccines, testing, and therapeutics	• Coverage for COVID-19 vaccinations will continue without cost-sharing. • Coverage for COVID-19 PCR and antigen tests and their administration will continue generally without cost-sharing when the test is ordered by a physician or certain other health care providers, such as physician assistants and nurse practitioners and performed by a laboratory. • People enrolled in MA plans can continue to receive COVID-19 PCR and antigen tests when the test is covered by Medicare, but their cost-sharing may change when the PHE ends. • Coverage of over-the-counter COVID-19 tests at no cost to the beneficiary ended with the end of the PHE since original Medicare does not generally pay for over-the-counter services and tests. However, some MA plans may continue to provide coverage of over-the-counter COVID-19 tests as a supplemental benefit. • There is no change in Medicare coverage of treatments for those exposed to COVID-19 once the PHE ends, and in cases where cost-sharing and deductibles apply now, they will continue to apply. • Generally, the end of the COVID-19 PHE does not change access to U.S. government (USG)-procured oral antivirals, such as Paxlovid and Lagevrio. As Paxlovid and Lagevrio transition to the commercial	• Coverage provided as a result of ARPA ended on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE. With the end of the COVID-19 PHE on May 11, 2023, this coverage requirement ended on September 30, 2024. • After that date, coverage of COVID-19 treatments and testing may vary by state. • Coverage of COVID-19 vaccinations for certain Medicaid eligibility groups may also vary by state after September 30, 2024. • Optional Medicaid coverage to uninsured

	Medicare	Medicaid
	market, Paxlovid will be available to Medicare beneficiaries at no charge through an agreement with Pfizer, while Ligorio coverage will be determined by Part D plans' coverage rules.[92]	individuals (implemented in 18 states and territories) for COVID-19 vaccinations, testing, and treatment ended with the end of the PHE.
Telehealth	• The Consolidated Appropriations Act, 2021 (CAA, 2021, (P.L. 116–260) made permanent certain telehealth flexibilities for mental health services: o For services for the diagnosis, evaluation, or treatment of a mental disorder: geographic restrictions were permanently removed, and a beneficiary's home was allowed to serve as an originating site for telehealth services paid for by Medicare. o Imposed an in-person visit requirement prior to receiving treatment of a mental disorder via telehealth and provided discretion to the Secretary to impose periodic in-person visit requirements as it deemed necessary. • In the CY 2022 Physician Fee Schedule final rule, CMS revised the regulation at 42 CFR § 410.78(a)(3) to permit the use of audio-only equipment for telehealth services furnished to patients in their homes under certain circumstances for purposes of diagnosis, evaluation, or treatment of a mental health disorder (including substance use disorder). • The Consolidated Appropriations Act, 2022 (CAA, 2022, P.L.117-103) extended many of the telehealth flexibilities that were available during the PHE for an additional 151 days following the end of the PHE and delayed in-person visit requirements for mental health services including: o Temporary extension of originating site requirements to allow beneficiaries to be located in any geographic location in the United States and in any setting including their home. o Temporary expansion of the definition of telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists. o Temporary extension of the authority to furnish certain telehealth services via audio-only technology.	• Most Medicaid telehealth flexibilities are not tied to the end of the PHE. Many state Medicaid programs utilized telehealth flexibilities long before the pandemic. • Authorized delivery of services using telehealth varies by state. • CMS encourages states to allow Medicaid and CHIP services to be delivered via telehealth.

[92] https://www.cms.gov/files/document/commercialcovid19oralantiviralsmemorevised20240220final.pdf

	Medicare	Medicaid
	○ Continued payment for telehealth services for RHCs and FQHCs using the methodology established for those telehealth services during the COVID-19 PHE. • The CAA, 2023 extended the above-mentioned statutory telehealth flexibilities through December 31, 2024. • In the CY 2024 Physician Fee Schedule final rule, CMS finalized refinements on their process to consider changes to the Medicare Telehealth Services List. In the final rule, CMS finalized the addition of codes to the Medicare Telehealth Services List on both a permanent and temporary basis, including adding health and well-being coaching services on a temporary basis, and Social Determinants of Health Risk Assessments on a permanent basis. • Pursuant to section 1899(l) of the Act, some Accountable Care Organizations (ACOs) may offer telehealth services that allow clinicians to care for patients without an in-person visit, in any geographic location and in the home.	

c. Preparing for Future Emergencies

CMS also wanted to ensure it would be prepared for future emergencies and therefore assessed which section 1135 waivers and flexibilities would be most useful in a future PHE. This assessment considered many factors, including statutory authority, impact on health and safety, risks to program integrity, and budget impact. CMS aimed to have this evaluation inform the development of a "playbook" of section 1135 waivers and flexibilities that CMS could use quickly if needed in response to a future emergency.

CMS documented key lessons learned, strengthening the agency's resiliency to future pandemic virus events, through publication of a redesigned Pandemic Plan in January 2021, based on knowledge and experience gained in the first year of the COVID-19 PHE.[93] The plan details the use of available waivers and flexibilities, includes a comprehensive inventory of agency processes and activities during a pandemic response, and defines a response structure that brings the operational and policy components together, expediting decision-making and accomplishing the goals of the agency's response. While the COVID-19 PHE was in effect, CMS continued to use the Pandemic Plan as a guidebook for evaluating all existing flexibilities.

CMS has also continued to collaborate with federal partners and the health care sector to ensure holistic preparation for future emergencies. In April 2022, CMS launched the revised CMS National Quality Strategy with a goal of ensuring that all persons receive equitable, high-quality, and value-based care. The strategy includes a resiliency goal. The CMS Framework for Health Equity, also released in 2022, set forth priority areas including standardizing data collection and analysis, strengthening the health care workforce, increasing provision of culturally and linguistically appropriate services, and identifying and eliminating barriers underserved communities face in accessing health care and coverage. These priorities are consistent

[93] CMS, "CMS Pandemic Plan v. 3.1 Public Release," January 11, 2021.

with a number of CMS and HHS initiatives and align with Executive Order 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government", (January 20, 2021).

2. External Feedback Received on Approaches

CMS reviewed external feedback on waivers from published peer-reviewed literature, policy briefs, government reports, letters to HHS and CMS, written statements from professional associations, and evaluations of states' approaches to waiver adoption for Medicaid and CHIP to complete this report. CMS also worked with independent third parties to conduct external interviews with providers and professional associations representing health systems, tribal and rural communities, clinicians, LTC providers and behavioral health professionals related to their experiences with section 1135 waivers and the impact of the section 1135 waivers on care delivery, workforce management, health equity, and quality measurement.

Early in the PHE, CMS tasked a contractor to develop an independent Coronavirus Commission for Safety and Quality in Nursing Homes. The Commission was created to conduct a review and comprehensive assessments of the impact of COVID-19 and CMS' actions, including but not limited to waivers and flexibilities, to help CMS inform immediate and future actions as well as identify opportunities for improvement.[94] The Commission's report was released on September 16, 2020 and contained best practices that emphasize and reinforce CMS strategies and initiatives to ensure nursing home residents were protected from COVID-19.

In May 2021, CMS also commissioned a contractor to conduct a mixed-methods study to learn about hospital, critical access hospital, and nursing home experiences in responding to the COVID-19 pandemic in light of emergency preparedness regulations and flexibilities. Through conversations with 30 providers across 10 states representing diverse experiences under the PHE, CMS identified key enablers for implementation (such as leadership, culture, and governance; infection prevention and control expertise; and local planning and coordination) and challenges (such as planning for underserved and vulnerable populations; data reporting; technical assistance; and managing federal, state, tribal, local, and territorial guidance) to consider during an emergency response.[95]

In September 2023, CMS awarded a contract to conduct external interviews with interested parties on CMS' use of waivers and flexibilities and the impact on their systems and practices. The following section summarizes relevant feedback received from the various communications channels as well as the independent external interviews. Many of the interested parties noted their desire to have certain waivers and policies continue beyond the PHE. It should be noted that inclusion of the comments from interested parties does not indicate CMS' agreement or imply that a specific action will be taken as a result of the feedback. CMS values comments received and considered evidence related to the health and safety of beneficiaries, stewardship of the Medicare Trust Fund, and administrative procedural requirements when considering any policy recommendation.

a. Communication and Coordination

Provider groups generally applauded CMS communications regarding waivers and associated flexibilities throughout the COVID-19 PHE. Interviewees commended CMS efforts to respond to provider needs, commenting on the timely release of waivers and additional clarifying language in response to provider feedback. Interviewees appreciated CMS commitment to communication during the PHE, reporting that CMS valued their insights and worked in partnership with providers. Provider groups appreciated CMS' various approaches to communications, including office hours, open door conversation sessions, written

[94] MITRE "Corporation. Coronavirus Commission for Safety and Quality in Nursing Homes Report: cms.gov/files/document/covid-final-nh-commission-report.pdf, September 16, 2020.

[95] Sheila C. Blackstock, BSN, MSM, JD, Jean D. Moody-Williams, RN, MPP, and Lee A. Fleisher, MD, Learnings Regarding Emergency Preparedness During the Public Health Emergency: A Mixed-Methods Study of Hospitals and Long-Term Care Facilities. https://catalyst.nejm.org/doi/full/10.1056/CAT.22.0152

FAQs, and direct contact with CMS staff members. Provider groups also appreciated how CMS assigned specific individuals to interface with different specialty societies, resulting in a faster exchange of information regarding waiver challenges and clarifications. Interviewees also valued how CMS leveraged direct real-world connections with providers to dispense information and resolve conflicting guidance from multiple federal agencies and/or states.

States appreciated CMCS's partnership and guidance throughout the PHE. States cited the toolkits, templates, and checklists as crucial for designing and operationalizing their emergency response. States appreciated CMCS' responsiveness to questions and valued their technical assistance. Communication between CMCS and states was critical to identify and address rapidly evolving needs.

Providers also suggested areas for improved communications. Several provider groups noted challenges with the clarity of several of the updated guidance documents, describing how it was sometimes difficult to quickly identify relevant changes. Several provider groups suggested that CMS should examine and review methods for distributing updated guidance and information on waiver flexibilities to providers to prepare for future PHEs. Suggestions included more clearly designating start/stop dates of new guidance, improved searchability of documentation, and callout boxes clarifying relevant updates on websites.

While interviewees noted that CMS did well in issuing section 1135 blanket waivers from the start of the PHE, they noted the need for more clarity on who could request individual waivers and how to submit the requests. Some interviewees noted that CMS' efforts to coordinate among different provider types was effective. However, some commented that SNFs and NFs experienced challenges in applying blanket waivers to their specific situations, and some waivers pertaining to LTC facilities were terminated while the PHE was ongoing, which was sometimes difficult to track.

Under section 1902(a)(73) of the Act, states must consult with Indian Health Programs and Urban Indian Organizations prior to the submission of any Medicaid or CHIP SPAs, waiver requests and proposals for demonstration projects likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations. Section 1135 authority can be used to modify the timing of when tribal consultation must be conducted, allowing states to shorten consultation or conduct consultation after the submission of a SPA. During the PHE, some states requested and received waivers to modify the timing of required tribal consultation. Tribes noted the continual need to be closely connected to decisions regarding timing of consultations on SPAs and waiver submissions and encouraged increased technical assistance and training for states on consulting tribes about submissions that directly impact them.

b. Vaccines

Coverage and payment for stand-alone vaccine counseling could help increase COVID-19 and other vaccination rates. With the onset of COVID-19 vaccine distribution in 2021, clinicians counseled beneficiaries about the need for COVID-19 vaccination and other recommended immunizations despite varying payment policies across Medicare and Medicaid programs. While Medicare paid for counseling through payment for other services, it was not always clear what could be billed if the beneficiary chose not to get vaccinated even after counseling, although CMS did issue Medicare guidance on when counseling could be billed in those circumstances. Under Medicaid, stand-alone vaccine counseling (i.e., counseling that was not provided during the same visit as vaccine injection or delivery) was required to be covered only for individuals under the age of 21 eligible for the Early and Periodic Screening, Diagnostic, and Treatment benefit.[96] [97] Clinician groups identified the importance of counseling vaccine-hesitant individuals to help stem the COVID-19 PHE[98] and urged HHS to continue to explore requiring all public programs to cover separate vaccine counseling including for counseling conducted using audio-only or audio/video telehealth services.[99]

[96] American Academy of Family Physicians, "Letter to Secretary Becerra," September 7, 2023.
[97] sho22002.pdf (medicaid.gov)
[98] Group of Six, "Letter to Administration Officials on Vaccine Counseling," November 1, 2021.
[99] Ibid.

Address challenges for clinicians as the COVID-19 vaccine transitions to the commercial market. While CMS worked diligently to help ensure that payment for COVID-19 vaccines would remain the same after the PHE declaration, (i.e. most beneficiaries would not incur cost-sharing), there was concern regarding access challenges if adequate supplies were not available from manufacturers or from pharmacies or other providers.[100] In addition, uninsured adults may have limited access to free vaccines and no coverage for the cost of treatments and tests. In recognition of these concerns, primary care clinicians encouraged CMS to address potential challenges through several strategies in the future, including: 1) prioritizing distribution of new vaccines to primary care; 2) ensuring fair Medicare and Medicaid payment rates that cover the cost of offering vaccines; 3) offering primary care providers buy-back programs with vaccine manufacturers; 4) providing separate payments for vaccine counseling; and 5) ensuring timely, equitable access to vaccines through the Bridge Access Program for adults without coverage.[101] The group recommended that CMS continue enhanced Medicare payment rates through 2024 and requested guidance for state Medicaid officials outlining waivers and resources to ensure fair payment for vaccines.

c. COVID-19 Testing

Continued coverage of COVID-19 tests will provide access for the most underserved populations. After the end of the PHE, coverage of COVID-19 testing has varied by payer. Coverage for laboratory tests has continued with generally no cost-sharing for traditional Medicare beneficiaries when tests are ordered by a health care provider. However, traditional Medicare coverage for over-the-counter COVID-19 tests ended with the PHE. MA plans were required to cover COVID-19 tests without cost sharing during the PHE and may continue to provide coverage for over-the-counter COVID-19 tests as a supplemental benefit. Medicaid coverage for COVID-19 tests will continue through September 30, 2024, after which coverage is expected to vary by state. While private insurers were required to cover testing, the requirement does not apply to tests furnished after the PHE termination. Therefore, coverage for over the counter and laboratory COVID-19 tests varies across private payers.[102,103]

Due to varying test coverage across payers and potential access issues for those at high risk for severe COVID-19 and/or hospitalization, several interested parties have supported HHS policies that continue coverage of COVID-19 tests after the end of the PHE. Interested parties called for HHS to continue coverage of up to eight over the counter COVID-19 tests for Medicare beneficiaries every month, noting that the tests are more accessible to high-risk, older adults. In addition, groups advocated for continuing to allow rural hospitals and CAHs the ability to screen patients offsite to prevent spread of COVID-19.[104] CMS has noted that it does not have the statutory authority to continue to cover over the counter tests post-PHE but appreciates the concerns raised by interested parties.

To increase access to COVID-19 testing, Section 6004(a)(3) of FFCRA authorized a new Medicaid eligibility group ("optional testing group") for previously uninsured individuals to receive Medicaid coverage for COVID-19 testing with 100 percent FMAP; the coverage for this group was later expanded under the ARPA to include coverage for COVID-19 vaccines and their administration and COVID-19-related treatment. In addition, states received 100 percent federal financial participation (FFP) for certain state Medicaid program administrative expenditures related to providing coverage for this optional eligibility group that would otherwise have been federally matched at 50 percent FFP. The statutory authority for this eligibility group expired at the end of the PHE. States reported that implementing the optional testing group required

[100] Centers for Medicare & Medicaid Services, "Transcript Hospital Association Office Hours Call on Ending of the COVID-19 Public Health Emergency," May 5, 2023.
[101] Ibid.
[102] Ibid.
[103] Department of Health and Human Services, "Fact Sheet: End of the COVID-19 Public Health Emergency," May 9, 2023.
[104] National Rural Health Association, "Letter to Secretary Xavier Becerra Re: End of the Public Health Emergency and Associated Flexibilities," February 21, 2023.

significant investment to determine beneficiary eligibility and enrollment, and coordinate benefits with the Provider Relief Fund. The CARES Act provided the largest amount of funding, $1.8 trillion, to combat both the health care crisis, as well as the ensuing economic fallout of the pandemic. It provided direct payments to individuals and grants to states, as well as the initial funding for the Provider Relief Fund and the Paycheck Protection Program. The Provider Relief Fund was established to provide health care providers with money to offset lost revenue, as well as help provide increased resources for the fight against the pandemic.

d. Telehealth

Telehealth flexibilities benefit healthcare providers and beneficiaries but may pose spending and program integrity concerns in the long-term.

During the COVID-19 PHE, relying on a combination of emergency rulemaking and new statutory authority, CMS issued section 1135 waivers and regulatory changes for Medicare to expand access to services delivered using telehealth, broadening the scope of services that could be provided via telehealth and the types of clinicians that can provide them. In addition, CMS issued section 1135 waivers and other flexibilities that allowed states to expand access to certain Medicaid services delivered using telehealth, and many states used these flexibilities to expand telehealth for their programs. These flexibilities permitted additional healthcare providers to deliver services using telehealth and allowed certain Medicare services to be furnished using audio-only methods,[100] such as telephones. Interviews with provider organizations and other interested parties highlighted how telehealth flexibilities were crucial in responding to the PHE. Provider organizations discussed how broad access to telehealth visits, use of non-HIPAA compliant platforms,[105] and use of audio-only technology for Medicare services enabled them to quickly adapt to providing virtual care. This helped providers maintain equitable access to care among older adults, rural populations, and populations without broadband internet access. They noted that telehealth waivers were also likely the most significant change in increasing workforce capacity, and expanding the types of providers that could provide and receive payment for services delivered using telehealth.

Initial data from qualitative studies and surveys show that telehealth flexibilities positively influenced beneficiary care while maintaining beneficiary satisfaction. According to a Government Accountability Office (GAO) review, analysis indicated that Medicare waivers and regulatory changes increased utilization of Medicare services delivered using telehealth and access to Medicare health care services that would otherwise not been available during the COVID-19 PHE.[106] Provider groups interviewed by GAO highlighted how Medicare telehealth waiver and regulatory flexibilities enabled delivery of continuous care during the early days of the PHE. Beneficiary groups identified similar benefits from telehealth flexibilities, describing how beneficiaries could access care from home, with the added benefits of receiving care in a timely manner, reducing travel time, and limiting exposure to in-person visits. State Medicaid officials interviewed by GAO reported that the increased use of telehealth during the PHE supported access to care for Medicaid beneficiaries and mitigated access obstacles, such as COVID-19 exposure and arranging for childcare.[102]

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[105] Separate from the section 1135 waivers, the HHS Office for Civil Rights (OCR), which enforces the HIPAA Privacy, Security, and Breach Notification Rules, issued a notification of enforcement discretion providing that OCR would not impose penalties for noncompliance with the HIPAA Rules in connection with a health care provider's good faith provision of telehealth using any non-public facing remote audio or video communication products during the PHE. *See*: 85 FR 22024 (Apr. 21, 2020).

[106] United States Government Accountability Office, "Medicare and Medicaid COVID-19 Program Flexibilities and Considerations for Their Continuation," May 19, 2021.

Several small qualitative studies support the GAO findings, suggesting that telehealth waivers and associated flexibilities increased access to care through several mechanisms. Shorter telehealth appointments enabled providers to see more patients in a day.[107]

The flexibility to deliver services using telehealth also helped reduce transportation barriers and inconvenience related to travel while increasing beneficiary comfort, enabling patients to seek needed care sooner through telehealth and attend more frequent or regular appointments.[108,109,110] Beneficiaries also reported high levels of satisfaction with telehealth during the COVID-19 PHE.[111] Further, providers reported that telehealth reduced deferred care, strengthened communication with caregivers, and facilitated health outreach and education.[112]

In a June 2023 report to Congress, the Medicare Payment Advisory Commission (MedPAC) shared initial findings based on comparing 2021 with 2018/19 baseline data that increased telehealth use for Medicare services during the PHE was associated with slightly improved access to care for some beneficiaries, slightly increased costs to the Medicare program, and little impacts on measured quality. However, MedPAC warned that the impacts of telehealth expansion through Medicare waivers could not be disentangled from other PHE-related impacts on spending and utilization. [113] Several studies found little to no increase in utilization of primary care during the PHE.[114,115,116] MedPAC updated its study using 2022 data, and instead found higher telehealth intensity areas associated with fewer clinician encounters and potentially lower total costs of care.[117]

The GAO cautioned that telehealth waivers and flexibilities could have longer-term effects on spending and quality of care and suggested careful monitoring and oversight to track and prevent potential fraud, waste, and abuse stemming from the waivers.[118] Likewise, both MedPAC and the Bipartisan Policy Center recommended strengthening fraud, waste, and abuse protections for telehealth services. Other organizations also emphasized the need for additional data and investigation into the impacts of telehealth flexibilities on billing and health care costs.

Interviews conducted by CMS with provider associations highlighted the importance of Medicare telehealth waiver flexibilities across the continuum of care. Representatives for independent practitioners and primary

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[107] Teresita Gomez et al., "A Qualitative Study of Primary Care Physicians' Experiences with Telemedicine During COVID-19," *Journal of American Board of Family Medicine*. 34; (2021): s61-s70.
[108] Medicare Payment Advisory Commission (MedPAC). *Report to Congress: Medicare and the Health Care Delivery System*. June 15, 2023.
[109] Erin Sullivan et al., "COVID-19's Perceived Impact on Primary Care in New England: A Qualitative Study," *Journal of American Board of Family Medicine* 35, no. 2 (2022): 265-273. 7
[110] National Academy for State Health Policy, "Seeking Patient Engagement to Sustain Telehealth Flexibilities into the Future," August 29, 2022.
[111] Raphael Agbali et al., "A Review of Audiovisual Telemedicine Utilization and Satisfaction Assessment During the COVID-19 Pandemic," *International Journal of Technology Assessment in Health Care* 38, no. 2 (2022): 1–11.
[112] Elizabeth Goldberg et al., "Perspectives on Telehealth for Older Adults During the COVID-19 Pandemic Using the Quadruple Aim: Interviews with 48 Physicians," *BMC Geriatrics* 22, no. 188 (2022). 8
[113] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Medicare and the Health Care Delivery System. June 15, 2023.
[114] Ram A Dixitet al., "The Impact of Expanded Telehealth Availability on Primary Care Utilization," *NPJ Digital Medicine* 5, no. 141 (2022).
[115] U.S. Department of Health and Human Services: Office of Inspector General, Telehealth Was Critical for Providing Services to Medicare Beneficiaries During the First Year of the COVID-19 Pandemic. March 15, 2022.
[116] RAND Corporation, Experiences of Health Centers in Implementing Telehealth Visits for Underserved Patients During the COVID-19 Pandemic, 2022.
[117] Medicare Payment Advisory Commission (MedPAC). Updated Analysis: Using Population-Based Outcome Measures to Assess the Impact of Telehealth Expansion on Medicare Beneficiaries' Access to Care and Quality of Care. Jun 13, 2024
[118] United States Government Accountability Office, "Medicare and Medicaid COVID-19 Program Flexibilities and Considerations for Their Continuation," May 19, 2021.

care providers discussed the importance of using telehealth for Medicare services to support practices, maintain continuity of care, and retain staff, especially the value of telehealth payment parity, waiving originating site requirements, allowing audio-only technology for Medicare telehealth visits, allowing providers to practice across state lines via telemedicine, expanding the list of providers and services that can be reimbursed by Medicare for telehealth services, and flexibility in telehealth technology platforms. Interested parties across the continuum of care emphasized how CMS' quick response to the PHE and willingness to offer flexibilities enabled timely, continuous service provision, while maintaining access for older and rural populations. It's important to note that the ability to permanently implement many of the PHE flexibilities adopted for telehealth services would require legislative action.

During the PHE, CMS encouraged Medicaid state agencies to consider authorizing delivery of covered services via telehealth, and states' adoption of service delivery via telehealth accelerated significantly, as did beneficiary utilization of telehealth.[119] While states still have questions about clinical effectiveness when delivering some services via telehealth (particularly when using certain modalities), many states reported the positive outcomes of telehealth expansion during the COVID-19 PHE. Furthermore, a small sample of state Medicaid agencies interviewed by CMS indicated that the benefits of telehealth use during the PHE included: reduced no-show rates; decreased reliance on non-emergency transportation for service provision; ability to engage individuals who were historically difficult to reach in services; and greater access for beneficiaries with limitations on time, such as difficulty making appointments due to work or caregiving responsibilities.[120]

According to a survey of Medicaid agency officials from 49 states and the District of Columbia, telehealth utilization by Medicaid beneficiaries decreased and/or leveled off in fiscal year 2022 but remained above utilization levels prior to 2020.[121] As the survey describes, when the COVID-19 PHE ended, two-thirds of the states either expanded or planned to expand telehealth policies in fiscal years (FY) 2022 or 2023. The survey results indicated that the most common policies included expansions of allowable telehealth modalities and services allowed to be delivered via telehealth; however, other policy changes, such as expansions of telehealth providers, allowable distant/originating sites, and payment parity, were also enacted. Despite the increase in telehealth utilization since 2020, many states still report quality concerns about its use, including privacy, billing and coding challenges, and the potential for fraud and abuse.[122]

e. Emergency Reporting

Modifying quality reporting program requirements enabled participating providers to focus on care delivery.

During the PHE, CMS granted extensions and exceptions for a variety of quality reporting requirements, including MIPS, Shared Savings Program, and other hospital and Post-Acute Care (PAC) quality reporting programs.[123]

In interviews, providers highlighted the value of waiving reporting requirements during the PHE. One primary care stakeholder organization emphasized that waiver extensions on filing deadlines for reporting requirements enabled smaller, independent practices to reallocate reporting resources to providing care and

[119] ASPE, https://aspe.hhs.gov/sites/default/files/documents/190b4b132f984db14924cbad00d19cce/Medicaid-Telehealth-IB-Update-Final.pdf
[120] Information was provided by five states—Colorado, Idaho, Maine, Massachusetts, and Wisconsin—during interviews conducted for, and described in, the "State Medicaid & CHIP Telehealth Toolkit Policy Considerations for States Expanding Use of Telehealth COVID-19 Version: Supplement #1." Information was also provided during follow-up interviews conducted with these same states for this toolkit.
[121] Kaiser Family Foundation (KFF), https://files.kff.org/attachment/REPORT-How-the-Pandemic-Continues-to-Shape-Medicaid-Priorities-Results-from-an-Annual-Medicaid-Budget-Survey-for-State-Fiscal-Years-2022-and-2023.pdf
[122] ASPE, https://aspe.hhs.gov/sites/default/files/documents/11bc151081feb0123fc80283874ab7af/medicaid-telehealth.pdf
[123] CMS, "Medicare COVID-19 PHE Waivers & Flexibilities (Active)," accessed January 10, 2024.

adapting to the demands of the PHE. Hospital representatives echoed similar benefits, indicating reduced reporting requirements enabled hospitals to redistribute staff previously focused on documentation and reporting to hospital floors and patient care while still ensuring hospitals could bill and receive payment for services.

e. Surge Capacity

Providing services outside a hospital setting was integral for hospitals in providing critical non-COVID-19 care.

In March 2020, CMS announced the Hospitals Without Walls waivers and flexibilities, allowing hospitals to provide services in applicable outside facilities, such as ambulatory surgery centers, Inpatient Rehabilitation Facilities, hotels, and dormitories.[124] Hospital associations noted that surge capacity waivers were "exactly what we needed," and Hospitals without Walls enabled hospitals to reach patients without requiring them to come into the hospital. The group also noted that the program addressed health equity issues, such as access to care and transportation.

Studies of the Hospital Without Walls waiver flexibilities have emphasized the practical benefits of expanding capacity while maintaining or improving quality of care. Evidence from a large New York health system emphasized the importance of the Hospitals Without Walls initiative and associated section 1135 waivers in enabling hospitals to develop surge capacity procedures and manage high demand for acute care beds during COVID-19 waves. The waiver allowed the hospital to bypass typical insurance authorization processes and enabled quick transitions of patients from acute care hospitals to post-acute care facilities, including inpatient rehabilitation facilities. Waiver flexibilities allowing for additional diagnoses to be considered for admissions to inpatient rehabilitation facilities and supported additional inpatient hospital bed capacity for COVID-19 patients, critical during surges of COVID-19 infections.[125] Hospitals Without Walls flexibilities also resulted in improved recovery outcomes by expanding capabilities of ambulatory surgery centers. In one study of atrial fibrillation ablation procedures, individuals receiving the procedure in an ambulatory surgery center had shorter overall length of stay than those who had received the procedure in a traditional hospital setting.[126]

CMS also expanded the flexibilities to allow AHCAH flexibilities on November 25, 2020, by waiving § 482.23(b) and (b)(1) of the Medicare Hospital Conditions of Participation and suspending the requirement for nursing services to be provided on premises 24 hours a day, 7 days a week.[127] These flexibilities allowed hospitals to provide inpatient-level care to selected beneficiaries in their homes.

Additional research highlighted the value of the AHCAH flexibilities in expanding access to care during the PHE, while identifying important considerations related to program implementation and patient safety under the Medicare Hospital Conditions of Participation. Hospitals urged continuation of the AHCAH waiver program and requested payment parity for inpatient and hospital at home care.[128,129] Extension of the AHCAH waiver in 2022 provided hospitals with more reliable future funding for the program, motivating more

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[124] CMS, "Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge Fact Sheet," March 30, 2020.
[125] Sheryl R. Levin MD, Andrew I. Gitkind MD, MHA and Matthew N. Bartels, MD, MPH, "Effect of COVID-19 Pandemic on Postacute Care Decision Making,"," Archives of Physical Medicine and Rehabilitation 102, no. 2 (2021): 323-330.
[126] William Zagrodzky et al., "Abstract 10427: Length of Stay After Atrial Fibrillation Ablation in a U.S. Ambulatory Surgical Setting Compared to a Hospital Setting," *Circulation* 144, (2021).
[127] CMS, "CMS Announces Comprehensive Strategy to Enhance Hospital Capacity Amid COVID-19 Surge," November 25, 2020.
[128] Kacik, Alex, "Providers Push for Payment Parity for Hospital-at-Home Programs," *Modern Healthcare*, February 22, 2022.
[129] Guinan, Maryellen and Painchaud, Abigail, "Essential Hospitals Advance Equity Through Hospital-At-Home Model," *American Essential Hospitals*, April 2022.

hospitals to sign up for and begin implementing their own hospital at home programs.[130] At the same time, some advocacy groups and experts have cautioned against logistical challenges and the risk of lower-quality care in the AHCAH program; critics have emphasized the importance of examining specific program aspects, such as the sufficiency of remote monitoring, the adequacy of providing emergency services within 30 minutes, the elimination of 24-hour nursing services, the capabilities of home health agencies to handle higher acuity level care, the financial and emotional implications of the program for family members, and the program's potential for fraud and abuse.[131,132,133]

Interviews with advocacy organizations emphasized similar support for surge capacity initiatives introduced during the PHE, emphasizing that Hospitals Without Walls and AHCAH flexibilities enabled hospitals and providers to better respond to community needs and provide more equitable care during the PHE. AHCAH enabled individuals to receive needed care who might otherwise have been unable to access care due to transportation and health issues.

As noted earlier, the CAA, 2023 extended the AHCAH waivers and flexibilities until December 31, 2024, and required a separate report to Congress. CMS released the required report on September 30, 2024. This study used the best-available quantitative and qualitative data on AHCAH to draw comparisons between the AHCAH and brick-and-mortar hospital inpatient comparison groups. The report presents the study findings and identifies future considerations to address existing data, analytic, and measurement limitations.

Increased inpatient capacity during the PHE by waiving the 3-day qualifying hospital stay (QHS) requirement for SNF admission. During the PHE, CMS used Section 1812(f) of the Act to effectively waive the requirement that Medicare-covered SNF stays be preceded by a 3-day qualifying inpatient hospital stay through a broadening of coverage for SNF stays.[134] The flexibility allowed hospitalized patients to be transferred to SNFs more quickly, making more inpatient beds available. The flexibility also helped prevent exposure to COVID-19 in hospitals by allowing patients to bypass the hospital and be admitted directly to a SNF. There was significant utilization of this flexibility during the PHE, where approximately 15 percent of total SNF stays were for non-COVID patients admitted under this flexibility, and the highest proportion of SNF stays under this waiver were admitted following an inpatient hospitalization of less than 3 days.[135] Currently, more than 60 percent of Medicare beneficiaries receive the SNF benefit through programs that contain additional implicit and explicit cost control mechanisms and are exempt from the 3-day QHS requirement (that is for, MA and certain ACO initiatives).[136]

The flexibility lifting the 3-day QHS requirement for SNF stays ended with the end of the PHE.[137] Advocates have recommended making the 3-day QHS waiver permanent and have supported regulation that counts hospital observation days as a QHS prior to SNF admission. Groups have noted that the hospital stay requirement, which dates to 1965, is outdated because hospital lengths of stay have decreased, and some services may be provided in outpatient settings. They asserted that requiring unnecessary inpatient hospital

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[130] Batt, Rosemary, and Eileen Appelbaum. "The New Hospital-at-Home Movement: Opportunity or Threat for Patient Care?" *Public Policy & Aging Report* 33, no. 2 (May 1, 2023).
[131] Ibid.
[132] National Nurses United. "Medicare's Hospital at Home Program is Dangerous for Patients", September 2022.
[133] Abraham Brody, Eve Dorfman, Christopher G. Caspers, and Tina R. Sadarangani. "What's next for Hospital at Home Programs in the United States: A Clarion Call for Permanent, Person-Centered Solutions." *Journal of the American Geriatrics Society* 71, no. 1 (November 2022).
[134] CMS, "Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19," May 10, 2023.
[135] Aurora, Marisa, Song, Annie, and Morley, Melissa, "SNF 3-Day Waiver Use During the COVD-19 Pandemic," *Avalere*, September 28, 2023.
[136] Center for Medicare Advocacy, "It's Time: Repeal the 3-Day Inpatient Hospital Requirement for Medicare Skilled Nursing Facility Coverage," February 10, 2022.
[137] CMS, "Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19," accessed January 11, 2024.

stays is a wasteful expense for Medicare. Additionally, advocates have called for the SNF benefit to extend to all Medicare members.

Recommendations to permanently eliminate the SNF 3-day QHS requirement have found support in some studies, but the potential for increases in SNF utilization and overall cost to the Medicare program should be considered. A CMS analysis of the SNF 3-day waiver for ACOs found that patients admitted under the flexibility had shorter lengths of stay, were more likely to be discharged home, and experienced similar outcomes to patients not admitted under the waiver, yet it is important to recognize that ACO initiatives contain additional cost controls implicit in their program design that may not be applicable in the FFS context.[138] Previous coverage expansions beyond the 3-day SNF QHS requirement on a national level have triggered dramatic spikes in SNF utilization, as with the 241 percent increase in SNF payments between 1988 and 1989 following the passage of the Medicare Catastrophic Coverage Act in 1988.[139]

Waivers that allowed for workforce expansion were impactful.

Workforce capacity is an ongoing concern and challenge among hospitals and providers across all communities, including rural, urban, and otherwise underserved communities. The ongoing workforce shortage grew worse during the COVID-19 PHE, and hospitals and providers emphasized the value of workforce flexibilities during the COVID-19 PHE. They noted that waivers that allowed flexibilities around licensure limitations, pathways to training and certification, remote supervision, practice across state lines, and enabling non-physicians to practice at their full scope helped maintain access to care. Interviewees noted that Medicare waivers for telehealth and temporary nursing aides were critical to providing sufficient coverage. Other interested parties highlighted that expanding certain roles, such as nurses or pharmacists, facilitated provision of care while supporting staffing needs. For instance, Medicare home care and hospice providers shared that telehealth expansions allowed physicians to remotely supervise nurses visiting a patient in the home, allowing for more comprehensive care.

States were successful in maintaining Medicaid provider viability through retainer payments to direct care providers.

States determined how to target retainer payments through criteria such as the PHE's financial impact on Medicaid providers, the state budget, and type of provider. Interviewees reported that increased payment rates were useful in addressing financial challenges, maintaining staffing, and furnishing personal protective equipment, particularly in LTC facilities. States that followed CMS guidance on payment rates found the implementation relatively straightforward. However, states found that increasing payment rates required significant coordination due to many different authorities (for example, SPAs and Appendix K amendments to section 1915(c) HCBS waiver programs) and limited information on providers receiving funds from federal assistance programs.

Additionally, community health center (CHC) providers indicated appreciation of Medicaid-specific waivers and flexibilities. As CHCs are some of the largest Medicaid providers, flexibilities such as freezing disenrollments, waiving prior authorization requirements, and out-of-state licensing flexibilities enabled providers to address care needs of vulnerable populations during the PHE.

Expanding types of providers and settings to provide home and community-based services (HCBS) maintained levels of in-home support during the PHE.

Through section 1135 waivers, CMS authorized state Medicaid programs to expand the types of providers eligible to provide HCBS (for example, waiving conflict of interest requirements allowing the same provider to provide case management and other HCBS) and to allow HCBS to be provided in alternative settings. States that modified both HCBS provider requirements and settings saw HCBS claims return to pre-pandemic levels by July 2020. States reported that allowing family members to deliver HCBS care in-home

[138] CMS, "Skilled Nursing Facility 3-Day Waiver Analysis of Use in ACOs 2014-2019," accessed January 10, 2024.
[139] ASPE, "Public Financing of Long-Term Care: Federal and State Roles," September 1994.

helped ensure continuity of care. However, the experience with expanded settings for other services was mixed. For example, under our authorities, a state allowed HCBS to be provided at Urban Indian Health Centers and had positive feedback; another state allowed adult daycare and residential rehabilitation providers to deliver services in-home, but faced challenges posed by staffing ratios and payment models. States found the section 1915(c) HCBS waivers were vital for keeping beneficiaries with home health and personal care needs living in their communities but recognized that it was challenging to navigate the various authorities for the flexibilities (e.g., 1135 waivers, SPAs, Appendix K, and 1115 waivers).

f. Expanding the Workforce in Long-Term Care Facilities for Ongoing Preparedness

LTC facilities utilizing waivers provided comments during the PHE and recommended certain policies and activities to continue beyond the end of the PHE. Interested parties requested that the following changes continue after the end of the PHE:

Flexibilities for LTC facility nurse aide training requirements. To address staffing shortages in LTC facilities during the PHE, CMS issued a blanket waiver under section 1135 that provided flexibilities for nurse aides (NAs) to complete certified nursing assistant (CNA) certification requirements.[140] Flexibilities included: 1) waiving the requirement that nursing facilities could not employ a NA for more than four months unless they completed their training; 2) allowing on-site work during the PHE to count towards the 75-hour training requirement; and 3) postponing the deadline for completion of 12 hours of in-service annual training.[141,142] CMS did not waive the requirement that employed nurse aides must demonstrate competency for nursing services.[143,144] The waivers ended in June 2022; however, NAs hired on or before the waiver had up to four months after waiver termination to complete training requirements. CMS also allowed for individual waiver requests from states and nursing facilities while the PHE was in effect.

While there is significant support for NA training flexibilities, some interested parties hesitated to extend such flexibilities. For example, some expressed concerns that the waiver allowed insufficiently trained NAs to become permanent CNAs.[145] They noted that CMS identified concerns related to resident care in LTC facilities during the waiver period and that CMS had ended the waiver to ensure that regulatory requirements uphold standards for care quality.[146]

One stakeholder noted in an interview that termination of the waiver did not consider that there was a backlog of NAs who needed to complete training and certification. Training sites for NAs did not open or did not have instructors due to the pandemic, so when the waiver was lifted, there was insufficient time for the high volume of NAs to complete certification requirements. To address delays, CMS allowed an exception if the facility or NA could demonstrate attempts at completing certification, although there was confusion regarding who could apply.[147]

Expanding the role of LTC facility clinicians other than physicians.

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[140] CMS issued a blanket waiver in 42 CFR § 483.35(d) and § 483.95(g)(1), with an exception to 42 CFR § 483.35(d)(1)(i) regarding temporary nurse aide certification requirements.
[141] CMS, "Updates to Long-Term Care (LTC) Emergency Regulatory Waivers issued in response to COVID-19," April 8, 2021.
[142] CMS, "Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19," May 10, 2023.
[143] CMS did not waive the requirement in 42 CFR § 483.35(d)(1)(i), still requiring that temporary nurse aides must demonstrate competency.
[144] CMS, "Updates to Long-Term Care (LTC) Emergency Regulatory Waivers issued in response to COVID-19," April 8, 2021.
[145] Center for Medicare Advocacy, "CMS Authorizes New Waivers of Nurse Aide Training Requirements for Nursing Facilities," September 1, 2022.
[146] CMS, "Update to COVID-19 Emergency Declaration Blanket Waivers for Specific Providers," April 7, 2022.
[147] Ibid.

CMS workforce capacity waivers for LTC facilities[148] allowed for: 1) physicians to delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist under the supervision of a physician; and 2) physicians to delegate any required physician visit to a nurse practitioner, physician assistant, or clinical nurse specialist. All clinicians (including physicians) had to comply with state scope of practice laws.[149] The waivers helped address workforce shortage issues, increase provision of care, maximize the use of medical personnel, and protect the health and safety of residents in LTC facilities during the PHE. Practices that authorized physician delegation of tasks to other clinicians saw higher quality of care for older populations and better interdisciplinary team management.[150]

Interviewees expressed support for continuing the two waivers for the LTC facilities, indicating that physicians should be able to delegate all tasks to clinicians other than physician providers and to decide when other clinicians can conduct physician visits. They also advocated for using telehealth to facilitate physician visits in rural LTC facilities, with all tasks completed by other clinician providers occurring under physician supervision.[151] Another health care system alliance encouraged CMS to provide physicians discretion on the use of telehealth as a means of direct supervision and requested that CMS streamline Medicare and state scope of practice requirements to reduce compliance burden on physicians.[152] While some interested parties advocated for expanded scope of practice, other physician groups expressed caution on scope of practice expansions for clinicians other than physicians and has advocated for physician-led care to ensure patient safety and provision of high-quality care.[153] A coalition of nursing associations advocated that CMS make permanent the regulatory waivers and flexibilities that allowed advanced practice registered nurses to practice to the full extent of their state scope of practice laws.[154]

g. Ramp down to End the PHE Waivers and Flexibilities After the End of a PHE

For future emergencies, interviewees suggested continual attention related to expiration or withdrawal of waivers, including those that end during the PHE and those that end with the conclusion of the PHE. Some interviewees suggested that health care organizations need a recovery period after the end of a PHE, in which waivers do not expire with the end of the PHE. For instance, one group mentioned that rural providers have yet to return to consistent patient volumes from the pre-PHE era, so extending some flexibilities beyond the end of the PHE would help alleviate rural health challenges. Some described the need for a glide path for the end of the COVID-19 PHE, where some flexibilities should extend beyond termination of the PHE while the delivery system adjusts to new realities going forward. Many noted that resources such as the CMS roadmap for the end of the COVID-19 PHE were useful tools to consider for future PHEs. Since the COVID-19 PHE has ended, interviewees suggested that CMS prepare a standard list of waivers and their use cases so that waivers could be issued more quickly and efficiently in future emergencies.

3. Evaluation of Areas of Program Integrity Vulnerability

Although the breadth of some waivers, and flexibilities, along with the speed in which they were implemented, made tracking potential program integrity risks challenging, CMS was able to accurately identify and effectively mitigate program integrity risks throughout the constantly changing landscape of the PHE. Waivers and flexibilities were implemented and issued in various forms, including through regulatory

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[148] CMS waived requirements in 42 CFR. § 483.30(e)(4) and 42 CFR. § 483.30(c)(3).
[149] CMS, "Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19," May 10, 2023.
[150] Brian J. Lichtenstein et al., "The Effect of Physician Delegation to Other Health Care Providers on the Quality of Care for Geriatric Conditions," *J AM Geriatr* 63, no. 10, (October 2015): 2164-2170.
[151] National Rural Health Association, "Letter to Secretary Xavier Becerra RE: End of the Public Health Emergency and Associated Flexibilities," February 21, 2023.
[152] Childs, Blair, "Letter to Administrator Chiquita Brooks-LaSure Re: Conclusion of Flexibilities Provided During the Public Health Emergency," Premier Healthcare Alliance, May 6, 2022.
[153] American Medical Association, "AMA Advocacy Efforts," December 13, 2023.
[154] https://www.aacnnursing.org/portals/0/PDFs/Policy/Letters/2023/3-31-23-HHS-APRN-Letter.pdf

and sub-regulatory vehicles, making the tracking and documentation processes more complex. In addition, some changes that were key to a robust industry response to the COVID-19 PHE created program integrity risks that were challenging to mitigate, leaving gaps that could lead to fraud or abuse in programs while the flexibilities were in place.

To account for these issues, CMS used the GAO Fraud Risk Management Framework to identify potential program integrity risks resulting from the COVID-19 PHE waivers and flexibilities. CMS reviewed each waiver, identified potential vulnerabilities associated with the waiver, and scored the vulnerability based on risk level. CMS used dashboards to track potential risks and vulnerabilities. Based on these assessments, CMS developed mitigation strategies to address those risks. CMS believes this approach was a robust and effective method of tracking and mitigating program integrity risks during a PHE and would likely employ a similar strategy in future PHEs.

CMS' mitigations resulting from this fraud risk analysis included activities such as claims data monitoring and other data analytics, policy changes and, when appropriate, swift investigative action. For example, CMS performed a geographic analysis to identify providers billing for a high percentage of services rendered to patients who were at great distances from practice locations. This analysis helped CMS to identify services that likely had not been provided at all, as well as detect inappropriately ordered drugs and devices. Other examples of potential program integrity risks and vulnerabilities identified included:[155]

- **Additional, unnecessary laboratory testing:** Along with a COVID-19 test, some laboratories performed additional unrelated laboratory tests. For example, some laboratories billed a COVID-19 test with expensive tests, such as large respiratory pathogen panels, antibiotic resistance, allergy, genetic, and cardiac panels. In addition, some laboratories billed unnecessary respiratory, gastrointestinal, genitourinary, and dermatologic pathogen code sets with the "not otherwise specified" code CPT 87798.
- **Other, additional, unnecessary services:** In addition to unnecessary laboratory testing, bad actors also offered free COVID-19 tests to Medicare beneficiaries, requesting personally identifiable information (PII) to bill Medicare for the test. However, this PII was then used to bill for unapproved and illegitimate services. For example, beneficiaries have been billed for patient visits when only a COVID-19 test was necessary or have been billed for other unnecessary services such as durable medical equipment in addition to their COVID-19 test. Beneficiaries were targeted in several ways, such as through telemarketing calls, text messages, social media posts, and door-to-door visits. Such approaches exploited the COVID-19 PHE waivers and flexibilities related to COVID-19 tests and often left beneficiaries to face potential harm or unexpected costs associated with Medicare denials of a claim for an unapproved test.

To ensure the integrity of Medicare-related section 1135 waivers and other flexibilities granted during the PHE to providers, health care facilities, and states, CMS initiated immediate, nationwide steps. Specifically, CMS:

- Took a record-breaking number of administrative actions, revoking the Medicare billing privileges of 256 medical professionals for their involvement in telemedicine schemes. This represents the largest number of adverse administrative actions resulting from a single administrative health care fraud investigative initiative.[156]
- Continued its revalidation efforts, which include regular revalidation cycles for all existing 2 million Medicare providers and suppliers. For example, in FY 2020, CMS initiated revalidation for more than 300,000 providers and suppliers. During this period, close to 182,538 providers and suppliers successfully completed revalidation and approximately 24,338 providers and suppliers were deactivated.

[155] Department of Health and Human Services, *Agency Financial Report, FY 2021*, accessed January 10, 2024.
[156] CMS, Medicare & Medicaid Program Integrity, FY 2020 Annual Report to Congress, accessed January 10, 2024.

Some states exercised the flexibility to temporarily cease revalidation for enrolled Medicaid providers during the COVID-19 PHE. CMS implemented several mitigation efforts to reduce the program integrity impact of the flexibility, including providing guidance to states and developing FAQs on "data compare"[157] to assist states performing revalidations, and extending revalidation due dates for states.[158]

CMS also launched initiatives to ensure the integrity of Medicaid-related section 1135 waivers and other flexibilities granted during the PHE to states. Specifically, CMS:

- Required States to revalidate Medicaid providers at least every five years and may rely on Medicare revalidation results to meet certain revalidation requirements for dually participating providers and suppliers. Some states temporarily ceased revalidation for enrolled Medicaid providers during the COVID-19 PHE. CMS in turn implemented several mitigation efforts to reduce the program integrity impact of this flexibility, including providing guidance to states and developing FAQs on "data compare" to assist states performing revalidations and extending revalidation due dates for states.[159]
- Transitioned the Medicaid Integrity Institute[160] from an in-person facility location to a virtual training and education environment, due in part to the COVID-19 PHE. Despite the change to a virtual environment, state interest and participation remained strong, consistent with previous years. The list of courses included a trend in Medicaid COVID Vulnerabilities, Payment Error Rate Measurement (PERM) Corrective Action Symposium, and an Education & Outreach for the Territories Workgroup.[160]
- Developed a risk assessment template[161] and instructional webinar[162], based off the GAO Fraud Risk Management Framework, for states to use when assessing their PHE flexibilities for risks. The webinar also identified potential risk assessment areas impacted by 1135 waivers and other COVID-19 flexibilities for states to consider.

In addition, CMS, along with law enforcement agency partners including the Department of Justice (DOJ), the HHS OIG, and others worked together to investigate and prosecute fraud from identified COVID-19 PHE risks and related schemes. The fraud, waste, and abuse mitigation work included data analyses and studies, targeted investigations, development of Fraud Prevention System models and edits, and implementation of new policies. CMS and federal law enforcement investigated and shared information on several fraud schemes directly associated with the COVID-19 PHE. Identity theft was a significant factor. Specific to the COVID-19 PHE, Department of Justice, HHS OIG, and CMS issued a fraud alert warning the public about allegations of fraud and abuse connected to vaccine distribution.[163]

Types of suspect activity included:[164]

- Requests for payment to get a vaccine, including deposits or fees.
- Requests for payment or offers of money to enhance ranking for vaccine eligibility (that is getting a better spot in line or on a wait list).
- Offers to sell or ship doses of vaccine for payment.
- Offers to purchase vaccine record cards containing personal identifying information and fraudulent vaccine cards.

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[157] CMS offers a data compare service for provider screening that allows a state to rely on Medicare's screening in lieu of conducting state screening.
[158] Ibid, 14
[159] Ibid, 14
[160] CMS, Medicare & Medicaid Program Integrity, FY 2021 Annual Report to Congress, accessed January 10, 2024.
[161] CMS, Medicaid and CHIP Learning Collaboratives, "Risk Assessment Template", July 2021.
[162] CMS, Medicaid and CHIP Learning Collaboratives, "Risk Assessment Tool for Evaluating COVID-19 Flexibilities and Waivers" July 15, 2021.
[163] Office of Inspector General, "Fraud Alert: COVID-19 Scams," February 28, 2023.
[164] Department of Health and Human Services, Agency Financial Report, FY 2021, accessed January 10, 2024.

C. Recommendations for Improved Approaches Regarding Section 1135 Waivers and other CMS Policies

Based on ongoing internal assessments and external feedback on waivers from published peer-reviewed literature, policy briefs, government reports, letters to HHS and CMS, written statements from professional associations, and evaluations of states' approaches to waiver adoption for Medicaid and CHIP, CMS has identified lessons learned from the experience of using section 1135 waivers and other flexibilities during the COVID-19 PHE. Such lessons can inform future disaster preparedness and response as well as promote a resilient health care system.

The coordinated efforts across all of government yielded many successes and interested parties found value in the communication and policies efforts implemented by CMS. The COVID-19 PHE also revealed opportunities to improve aspects of the health care system, including streamlining regulations; incorporating advances in interoperability and exchange of data, technology, connectivity, operations, and preparedness; improving assessment of needs and gaps in the health care system; and aligning across programs within and outside of government. The COVID-19 PHE also underscored the need to address underlying disparities in health and health care outcomes, access, and quality across the health care delivery system.

The following recommendations originate from a variety of inputs as mentioned throughout this report. The recommendations not only address the lessons learned from implementation of section 1135 waivers and other flexibilities but also addresses issues that were either pre-existing and exacerbated by the pandemic or new challenges that arose during the PHE for which the agency is giving consideration for future emergencies. CMS continuously evaluated the impact of the section 1135 waivers and flexibilities from the beginning of the PHE and therefore has already started to implement several of the recommended actions as noted in the narrative that follows:

1. **Maintaining access to care and provider capacity through telehealth: Explore expansion of Medicare telehealth opportunities that will provide the ability to increase workforce capacity and support health care providers in delivering and receiving payment for services delivered using telehealth.**

    Physician Fee Schedule (PFS): During the PHE, CMS was able to use combination of emergency regulations and waiver authority, including new Medicare waiver authority provided by Congress, to expand the range of practitioners who were able to bill for Medicare services delivered via telehealth and waive the geographic and location requirements to enable telehealth services to be furnished anywhere in the U.S. including in the beneficiary's home for the duration of the PHE.

    The Medicare statute specifically limits the types of practitioners that can provide telehealth services. CMS has the authority to adjust other related policies through rulemaking, such as specifying the required level of supervision by the billing clinician when services are provided by their clinical staff incident to their professional services. For example, CMS generally specifies direct supervision for these services, which requires the supervising physician or practitioner to be "immediately available" to furnish assistance and direction during the service. CMS made regulatory changes during the PHE for COVID-19 to include "virtual presence" of the supervising clinician through the use of real time audio and video technology under certain circumstances.

    CMS will continue to explore the feasibility of increasing workforce capacity through services delivered using telehealth within existing statutory authorities.

    - **RHCs and FQHCs:** During the PHE and through December 31, 2024, RHCs and FQHCs can bill Medicare as a distant site for services delivered using telehealth through waiver authority provided by Congress. Similar to services under the PFS, CMS also has the

authority to adjust other related policies for RHCs and FQHCs, such as defining "direct supervision," which requires the supervising physician or practitioner to be "immediately available" to furnish assistance and direction during the service, to include "virtual presence" of the supervising clinician through the use of real time audio and video technology.

In the CY 2022 PFS final rule with comment (86 FR 65211), CMS revised the regulatory requirement that an RHC or FQHC mental health visit be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner. CMS revised the regulations under 42 CFR. § 405.2463 to state that an RHC or FQHC mental health visit could also include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. CMS will consider exploring options for expanding telecommunication technologies in the RHC and FQHC settings within the limit of statutory authority, to align with the telehealth policies implemented under the PFS.

- **Hospital Outpatient Prospective Payment System (OPPS):** In the 2023 OPPS final rule, CMS established specific codes describing mental health services furnished to beneficiaries in their homes through communication technology by clinical staff of the hospital, which allowed hospitals to bill for these services when furnished by hospital staff after the COVID-19 PHE. In the CY 2025 OPPS proposed and final rules, CMS acknowledged that it has generally aligned payment policies for outpatient therapy, diabetes self-management training (DSMT), and medical nutrition therapy (MNT) services furnished remotely by hospital staff to beneficiaries in their homes with policies for Medicare telehealth services. CMS stated that, to the extent that therapists and DSMT and MNT practitioners continue to be distant site practitioners for purposes of Medicare telehealth services, the agency anticipated aligning its policy for these services with policies under the PFS and continuing to make payment to the hospital for these services when furnished by hospital staff.
- **Medicare Opioid Treatment Program (OTP) Benefit:** CMS allows for substance use counseling, individual and group therapy, and initiation of treatment with buprenorphine (as authorized by Drug Enforcement Administration (DEA) and Substance Abuse and Mental Health Services Administration (SAMHSA) at the time the service is furnished) to be furnished via audio-video or audio-only telecommunications, if audio-video technology is not available to the patient. Additionally, CMS made permanent the flexibility for furnishing periodic assessments via audio-only telecommunications beginning January 1, 2025, so long as all other applicable requirements are met, to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished.
- **Home Health Prospective Payment System:** Current regulations (42 CFR. § 424.22) already allow that the face-to-face encounter for home health certification can be performed via telehealth in an approved originating site. Section 1895(e) of the Act governs the home health prospective payment system (PPS) and provides that services delivered using telehealth cannot substitute for a home visit as part of the plan of care or for purposes of patient eligibility or payment under the Medicare home health benefit and home health PPS. However, there is nothing to preclude a home health agency from adopting telemedicine or other technologies that they believe promote efficiencies when consistent with the plan of care, but there is no separate payment for those technologies under the Medicare home health benefit. Home health agencies (HHAs) may include the costs of telecommunications technology as an allowable administrative cost (that is, operating expense), if the technology is used by the HHA based on the plan of care.

2. **Maintaining workforce capacity during a PHE: Examine regulations to determine if there are areas that allow for strengthening workforce capacity through expansion of the scope of practice for clinicians other than physicians.**

    - **PFS:** During the PHE, CMS adjusted regulations and policies to expand flexibilities for how practitioners who independently bill Medicare could furnish or supervise Medicare covered services. Specifically, CMS defined direct supervision, which requires the supervising physician or practitioner to be "immediately available" to furnish assistance and direction during the service, to include "virtual presence" of the supervising clinician through the use of real time audio and video technology. These actions may have contributed to increased workforce capacity and patient access to services. CMS will consider addressing this topic in possible future rulemaking.

    - **RHCs and FQHCs:** During the PHE and through December 31, 2024, RHCs and FQHCs were permitted to bill Medicare as a distant site for services delivered using telehealth through temporary statutory authority provided by Congress. Similar to services under the PFS, for RHCs and FQHCs, CMS also has the authority to adjust other related policies, such as defining direct supervision, which requires the supervising physician or practitioner to be "immediately available" to furnish assistance and direction during the service, to include "virtual presence" of the supervising clinician through the use of real time audio and video technology and will consider changes in this area.

      Additionally, in the CY 2022 PFS final rule with comment CMS revised the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner. CMS revised the regulations under 42 CFR.§ 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. CMS will consider exploring options for expanding telecommunication technologies in the RHC and FQHC settings to align with the telehealth policies implemented under the PFS to expand workforce capacity.

    - CMS will continue to review its regulations to determine what other opportunities exist to ensure that practitioners can practice as allowed by their license and in accordance with the state laws for the states in which they practice.

3. **Strengthening the nation's health, safety and quality infrastructure that will be sustainable and beneficial during a national emergency: Increase preparedness for future public health emergencies and resiliency in the health system.**

    - CMS issued a public call to action issued in February 2022 in a publication entitled "Health Care Safety during the Pandemic and Beyond — Building a System That Ensures Resilience." CMS announced its intent to join leaders from throughout the health care ecosystem in reviewing safety practices and seeking better and more deeply embedded solutions that also help to close health disparities. CMS is already working to expand the collection and use of data on safety and quality indicators and developing safety metrics that draw on the rich clinical data captured digitally in electronic medical records, which incorporate information from all health care payers. A strong and resilient system will be

more likely to withstand the pressures of an emergency and lead to better processes as noted in the "Learnings Regarding Emergency Preparedness During the Public Health Emergency: A Mixed-Methods Study of Hospitals and Long-Term Care Facilities."

- In 2022, the agency launched the CMS National Quality Strategy (NQS), an ambitious long-term initiative that aims to promote the highest quality outcomes and safest care for all individuals. The CMS National Quality Strategy focuses on a person-centric approach from birth to end of life as individuals' journey across the continuum of care, from home or community-based settings to hospital to post-acute care, and across payer types, including Traditional Medicare, MA, Medicaid and CHIP and Marketplace plans. The CMS National Quality Strategy builds on previous efforts to improve quality across the health care system, incorporates lessons learned from the COVID-19 PHE, and addresses the urgent need for transformative action to advance towards a more equitable, safe, and outcomes-based health care system for all individuals. Fostering a more resilient health care system that is better prepared to respond to future emergencies is included as a specific goal of the NQS. CMS will work to implement the NQS over the next several years for health care system sustainability.
- CMS' Quality Innovation Network (QIN) – Quality Improvement Organization (QIO) program assists providers with high quality, hands-on quality improvement assistance in meeting their needs, and the health care quality and safety goals for beneficiaries. In contracting with Network of Quality Improvement and Innovation Contractors (NQIICs) for 2024–2029 to provide expert health care quality improvement services, CMS plans to promote optimal health and well-being through improved quality of care, equity, and outcomes for Medicare beneficiaries. CMS gave public notice of intent to issues task orders under the NQIIC Indefinite Delivery Indefinite Quantity contract in October 2023 and released the official solicitation in July 2024. The Scope of Work prioritizes emergency preparedness to support resilience in the health care system based on lessons learned throughout the pandemic.

4. Protecting the Underserved: Ensure policy development and implementation activities consider and protect underserved populations.

- CMS will continue to explore opportunities to enhance use and coverage of telehealth and other virtual services where appropriate to deliver high-quality care in rural, tribal, and geographically isolated areas. During the COVID-19 PHE, CMS utilized its authority under section 1135 of the Act (as amended during the PHE), along with regulatory authority, to implement a variety of temporary waivers and flexibilities for Medicare telehealth and other virtual services, including allowing payment for Medicare services delivered using telehealth any location in the U.S. including the patient's home, and permitting the use of audio-only technology to deliver services under certain circumstances. As CMS continues to examine lessons learned from the COVID-19 pandemic, the agency has made permanent via regulation certain temporary flexibilities services delivered using telehealth, including for mental and behavioral health care services and treatment of substance use disorders. CMS has released multiple toolkits on telehealth, like the State Medicaid & CHIP Telehealth Toolkit to support state policymakers in their efforts to expand use of telehealth services in Medicaid programs, and the Coverage to Care toolkit to aid health care providers in using telehealth, including considerations for rural and other underserved populations.[165] CMS also contributes to HHS resources such as Telehealth.hhs.gov.

[165] https://www.cms.gov/files/document/cms-geographic-framework.pdf

- On December 10, 2024 CMS updated the Medicaid and CHIP Informational Bulletin (CIB) that was released detailing opportunities to cover clinically appropriate and evidence-based services and supports that address health-related social needs (HRSNs), such as housing instability or food insecurity. The CIB summarizes HRSN services CMS considers allowable via various authorities, such as section 1115 demonstrations, SPAs, and section 1915 waivers. This guidance demonstrates CMS' commitment to addressing social determinants of health and the impact they have on the individuals, families, and children who rely on Medicaid and CHIP.

- On August 1, 2023, via IPPS, CMS finalized a change to the severity designation of the three ICD-10-CM diagnosis codes describing homelessness (e.g., unspecified, sheltered, and unsheltered) from non-complication or comorbidity to complication or comorbidity, based on the higher average resource costs of cases with these diagnosis codes compared to similar cases without these codes. As SDOH diagnosis codes are increasingly added to billed claims, CMS plans to continue to analyze the effects of SDOH on severity of illness, complexity of services, and consumption of resources. In FY 2023, CMS also finalized Hospital Commitment to Health Equity measure beginning with the CY 2023 reporting period that will impact FY 2025 payment determination. Lastly, CMS finalized the "Screening for Social Drivers of Health" and "Screen Positive Rate for Social Drivers of Health" measures beginning with voluntary reporting in the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period with an impact on FY 2026 payment determination.

- CMS will continue to proactively establish and test a mechanism and pathways for bidirectional information sharing about local disparities, needs, barriers, opportunities, and other relevant information to the public health emergency with CMS partner organizations including QIOs, patient navigators, MACs, and others. CMS can work with these partner organizations to ensure they can receive information and have a plan in place to understand and use available data to: 1) identify emerging local needs within specific communities and service areas; 2) address underlying and emerging disparities revealed by the data, and; 3) report and share back conditions, needs, and opportunities on the ground in local communities with CMS to help inform policy and program decisions with a local, real-time equity lens. Additionally, CMS can explore opportunities to strengthen and align business continuity requirements for contracted entities and provide education on inclusive disaster planning. Disruptions in operations, particularly during a disaster, may disproportionately impact underserved populations and those with certain health-related social needs (as well as the providers that care for these populations).

5. **Maintaining health system capacity and resiliency: Continue to explore and educate facilities on flexibilities available within CMS regulations to expand facility surge capacity during and outside of a PHE.**

    - CMS will continue to inform hospitals about flexibilities available under the Emergency Medical Treatment and Labor Act (EMTALA).[7] For example, in December 2023, in anticipation of possible increases in cases of influenza, COVID-19, and RSV, CMS issued a fact sheet reinforcing existing guidance to remind hospitals of the flexibilities available under EMTALA when emergency departments are experiencing surges in demand for emergency care and services. The fact sheet reinforces previous guidance regarding the options hospitals may utilize to increase surge capacity in their facilities and assist in maintaining compliance with the EMTALA requirements at 42 CFR. § 489.24 and the related requirements at 42 CFR. § 489.20(l), (m), (q) and (r) when emergency departments

are experiencing extraordinary surges in demand. These options include screening sites on hospital campuses, and at off-campus, hospital-controlled sites.

- CMS will continue to make the SNF 3-day stay rule flexibility available when deemed necessary. There are certain Shared Savings Program (SSP) participation options (known as tracks) and CMS Center for Medicare and Medicaid Innovation (Innovation Center) models that offer a 3-Day SNF Waiver. Some of the models include the Accountable Care Organization Realizing Equity, Access, and Community Health (ACO REACH) Model l, the Comprehensive Care for Joint Replacement Model, and the Bundled Payments for Care Improvement Advanced Model. The SSP tracks and Innovation Center models that offer a 3-Day SNF Waiver allow participants using the waiver to offer SNF services without a prior 3-day inpatient hospitalization when the patient is admitted to a SNF included on a CMS approved list for SSP or the specific Innovation Center model.

- As previously noted, the CAA, 2023 extended the CMS AHCAH initiative through December 31, 2024. In addition to extending waivers and flexibilities for physical environment requirements in the home and telehealth flexibilities, the law requires hospitals to provide additional data to CMS to monitor the quality of care. As required by the statute, CMS released a report on September 30, 2024. This study used the best-available quantitative and qualitative data on AHCAH to draw comparisons between the AHCAH and brick-and-mortar hospital inpatient comparison groups. The report presents the study findings and identifies future considerations to address existing data, analytic, and measurement limitations.

6. **Enhancing data monitoring systems: Consider ways to collect authorized data in an efficient manner to inform emergency efforts, particularly when issuing blanket waivers.**

    - CMS will consider opportunities to better use utilize existing collections of payment data to monitor CMS' policy response. This could include exploring opportunities to monitor uptake and usage of blanket waivers (e.g., using post-hoc imputation based on claims data). It also could include developing data models to better understand how utilization of individual waivers is likely to change during emergencies. This could help ensure that CMS is able to interpret utilization patterns under emergency circumstances.

    - CMS will consider additional ways to adjust waivers and other policies to the state of the emergency and to evaluate whether they are being used as intended or are either helping or introducing unintended negative impacts or harm to individuals served by CMS programs. This would help determine if policies are no longer needed, or whether they are impacting communities as intended or causing unanticipated, unintended, or differential impacts on different geographies or underserved communities.

7. **Administrative Processes: Identify and implement process improvements in the execution of section 1135 waivers during a PHE.**

    - CMS is pleased that many providers found the CMS processes and communication during the pandemic helpful. The agency appreciates the feedback that was received. CMS will continuously work toward improving processes related to issuing and communicating with provider communities about the availability of section 1135 waivers including continuing education on who can request individual waivers and how they can make the requests. CMS will also examine approaches to enhance the usability of waiver and regulatory documentation and updates, e.g., searchability of documentation so that providers can

quickly identify what is new or has changed. CMS will work to ensure continued coordination with MACs, so they are clear on what is paid for and what is not when a flexibility is in place. CMS continues to work across all of HHS to ensure alignment and compatibility of section 1135 waivers with policies and guidance from other federal agencies and individual states. CMS will continue to ensure communications and outreach by providing updated information on our public facing resources including websites and 1-800 numbers as well as ensuring opportunities for listening sessions and office hours.

- CMS will continue the practice of a whole-agency approach to address emergency needs of the health care community to ensure access to quality services. The COVID-19 Workgroup served as a model for future events and CMS has institutionalized these efforts through its Emergency Preparedness & Response Operations (EPRO) in the Office of the Chief Operating Officer. EPRO is further refining an organized and coordinated decision-making framework to manage all-hazard incidents and events affecting our systems, processes, and structures at CMS.

IV. Summary and Conclusions

CMS recognizes the countless hours of effort from America's health care workers in all settings and the incredible sacrifice of patients, residents, clients, families, and caregivers that were called upon to navigate the uncertainties of the COVID-19 pandemic. CMS processed an unprecedented number of section 1135 waiver requests to address the often rapidly changing needs of Medicare, Medicaid, and CHIP beneficiaries and providers. Because Medicare is operated at the federal level while Medicaid and CHIP are primarily state-run, the programs faced different challenges and required different policy actions.

The scale and intensity of the COVID-19 pandemic required a "whole-of-CMS" approach to facilitate the agency's response. Intra-agency coordination revolved around the COVID-19 Workgroup, comprising leaders across CMS who met frequently to make policy decisions. CMS collaborated with partners across HHS, other federal government agencies, and states to disseminate information about COVID-19 waivers and flexibilities and to discuss evolving policy responses.

Statutory authorities and regulatory flexibilities were used effectively during the COVID-19 PHE to expand access to vaccines, therapeutics, and COVID-19 testing; to broaden provisions for delivery of Medicare services using telehealth; to enable improved emergency reporting; to build surge capacity in the health care workforce; and to strengthen COVID-related services delivered as part of LTC, whether in a LTC facility or in alternate settings of care. The provisions of several waivers and flexibilities have been extended via statute beyond the end of the PHE, to meet ongoing needs. There has been limited research to assess the efficacy of waivers and flexibilities, for example on telehealth and on the Hospital at Home model.

As noted throughout this report, interested parties noted the following waivers as being most helpful:

- Telehealth waivers and state flexibilities were critical for maintaining access to care, supporting health equity, increasing workforce capacity, and supporting financial viability of health care organizations and providers.
- Surge capacity initiatives introduced during the PHE, especially Hospitals Without Walls and AHCAH flexibilities, enabled hospitals and providers to better respond to community needs and provide more equitable care during the PHE.
- Bypassing the 3-day qualified hospital stay QHS requirement for SNF admissions received widespread support from health care organizations.
- Waivers that allowed for workforce expansion were among the most utilized and impactful flexibilities during the PHE. States were successful in maintaining provider viability through retainer payments to direct care providers.

CMS' policy response enabled millions of Americans to access critical medical products and services and helped ensure medical practices stayed open and were able to quickly shift to alternative forms of patient interaction during the COVID-19 pandemic. CMS used a combination of emergency authority waivers, regulations, enforcement discretion, and sub-regulatory guidance to ensure access to care and give health care providers the flexibilities needed to respond to COVID-19 and help keep people safer. Many of these waivers and broad flexibilities terminated at the end of the PHE, as they were intended to address the acute and extraordinary circumstances of a rapidly evolving pandemic and not to replace existing requirements. Several flexibilities were made permanent through either Congressional action or regulatory change, where the temporary change warranted a permanent solution to better serve beneficiaries. CMS also identified several areas of improvement that will help with other emergency situations in general and particularly one of this size and scope.

CMS appreciates the positive comments received during the independent evaluation. Likewise, CMS appreciates the recommendations for improvement and takes this responsibility seriously. Ensuring the health and safety of its beneficiaries is the priority. CMS realizes the threat of emergency events continues to grow with climate related events, cybersecurity occurrences, continuing presence of respiratory diseases such as influenza, COVID-19 and RSV and unknown threats. CMS will remain vigilant in its efforts to keep America safe even during the time of an emergency event, recognizing that it will take a coordinated response from the country as a whole and take action as necessary. On August 1, 2024, CMS renewed and revised the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) data reporting requirements for data related to various respiratory infections, including COVID-19. Sustained data collection and reporting of respiratory illnesses outside of emergencies will help ensure that hospitals and CAHs have appropriate insight related to evolving infection control needs. Specifically, CMS is requiring that, beginning on November 1, 2024, hospitals and CAHs electronically report information about COVID-19, influenza, and RSV on a schedule specified by the HHS Secretary. And, in the event of a declared PHE for an acute respiratory illness, the Secretary may require additional reporting. Additionally, Beginning January 1, 2025, LTC facilities will be required to electronically report data on COVID-19, influenza, and respiratory syncytial virus (RSV) in a standardized format, replacing the current COVID-19 reporting requirements that are set to expire in December 2024.

Thank you for the opportunity to submit this critically important Report to Congress.

Appendix A: Acronyms

Acronym	Definition
ACO	Accountable Care Organization
AHA	American Hospital Association
AHCA	American Health Care Association
AHCAH	Acute Hospital Care at Home
ARPA	American Rescue Plan Act
ASC	Ambulatory Surgery Center
ASPE	Assistant Secretary for Planning and Evaluation
CAA	Consolidated Appropriations Act
CAH	Critical Access Hospital
CARES	Coronavirus Aid, Relief, and Economic Security Act
CCSQ	Center for Clinical Standards and Quality
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CLIA	Clinical Laboratory Improvement Amendments
CMCS	Center for Medicaid and CHIP Services
CMS	Centers for Medicare & Medicaid Services
CNA	Certified Nursing Assistant
CPI	Center for Program Integrity
CPT	Current Procedural Terminology
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FFCRA	Families First Coronavirus Response Act
FFS	fee for service
FMAP	Federal Medicaid Assistance Percentage
FQHC	Federally Qualified Health Center
FR	Federal Register
GAO	Government Accountability Office
HCBS	Home- and Community-Based Services
HCPCS	Healthcare Common Procedure Coding System
HHA	Home Health Agency
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Resources and Services Administration
ICF-IID	Intermediate Care Facilities for Individuals with Intellectual Disabilities
IFC	Interim Final Rules with Comment Period
IRF	Inpatient Rehabilitation Facility
LTC	Long-term Care
LTCH	Long-Term Care Hospital
MDS	Minimum Data Set
MIPS	Merit based Incentive Payment System
NAHC	National Association for Home Care & Hospice
NASMD	National Association of State Medicaid Directors

Acronym	Definition
NCAL	National Center for Assisted Living
NH	Nursing Home
NRHA	National Rural Health Association
OMB	Office of Management and Budget
OPDIV	Operating Divisions
OPPS	Outpatient Prospective Payment System
PAC	Post-Acute Care
PASRR	Pre-Admission Screening and Annual Resident Review
PHE	Public Health Emergency
QHS	Qualified Hospital Stay
RHC	Rural Health Clinic
RSV	Respiratory syncytial virus
SAMHSA	Substance Abuse and mental Health Services Administration
SME	Subject Matter Expert
SNF	Skilled Nursing Facility
the Act	Social Security Act
VCC	Vulnerability Collaboration Council

Appendix B. Medicaid and Medicare COVID-19 PHE Regulations, Waivers, and Flexibilities: Vaccines and Therapeutics presented for purposes of illustration of what was in place during the time of the Pandemic and not necessarily reflective of the current time.

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations
November 5, 2021	**Hospital Conditions of Participation (CoP) for COVID-19 Vaccinations.** Allowed for hospital and community administration of COVID-19 vaccines, the following language was incorporated into regulation for the duration of the PHE: 42 CFR. § 482.23 Condition of participation: Nursing services. (c) Standard: Preparation and administration of drugs. (3) With the exception of influenza, pneumococcal, and COVID-19 vaccines (either currently approved by the FDA or authorized under an FDA Emergency Use Authorization), which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with state law and hospital policy, and who is responsible for the care of the patient. On August 1, 2024, CMS renewed and revised the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) data reporting requirements such that, beginning on November 1, 2024, hospitals and CAHs electronically report information about COVID-19, influenza, and RSV on a schedule specified by the HHS Secretary.	482.23 1135 Waiver (blanket waiver)
November 6, 2020	**Medicare Coding and Payment for COVID-19 Vaccine.** CMS established Medicare Part B coverage and payment for a COVID-19 vaccine and its administration. CMS continued to pay approximately $40 per dose for administering COVID-19 vaccines for Medicare beneficiaries through the end of the year in which the Secretary ended the EUA declaration for drugs and biologicals with respect to COVID-19. Effective January 1 of the year following the year that the EUA Declaration ends, CMS set the payment rate for administering COVID-19 vaccines to align with the payment rate for administering other Part B preventive vaccines.	Section 1861(s)(10) of the Act. Section 3713 of the CARES Act (amended) Regulation Implemented in IFC 4: CMS-9912-IFC (85 FR 71145) at 42 CFR. § 410.152

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations
November 21, 2020	**COVID-19 Monoclonal Antibodies.** The FDA issued EUAs for monoclonal antibody therapies used for post-exposure prophylaxis or treatment of COVID-19. The FDA also issued EUAs for monoclonal antibody products used as a pre-exposure prophylaxis (PrEP) of COVID-19 in adults and pediatric patients with certain conditions. CMS covered monoclonal antibodies used for post-exposure prophylaxis or treatment of COVID-19 under the Part B vaccine benefit, through the end of the year in which the Secretary ended the EUA declaration for drugs and biologicals with respect to COVID-19. CMS will continue coverage for COVID-19 monoclonal antibodies used for prevention (PrEP) under the Part B vaccine benefit. CMS does not pay for the COVID-19 monoclonal antibody product when a health care setting has received it for free.	42 CFR. § 410.57(c) and 410.152(h), for COVID-19 PrEP mAbs. 86 FR 65193 87 FR 69988-93
May 21, 2021	**COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff.** CMS revised the infection control requirements that LTC facilities (Medicaid nursing facilities and Medicare skilled nursing facilities, also collectively known as "nursing homes") and intermediate care facilities for individuals with intellectual disabilities (ICFs-IID) must meet to participate in the Medicare and Medicaid programs. These revisions for LTC facilities and ICF-IIDs established requirements to offer and provide the COVID-19 vaccine to residents/clients, and staff, and requirements to offer and provide education on the COVID-19 disease and vaccine to residents/clients, and staff.	42 CFR Part 483 revised 42 CFR. § 483.80(d) 42 CFR. § 483.430(f) 42 CFR. § 483.460(a)(4) Regulation IFC 5: CMS-3414-IFC

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations
November 5, 2021	**Omnibus COVID-19 Health Care Staff Vaccination.** CMS revised the requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs. These changes were necessary to help protect the health and safety of residents, clients, patients, Program of All-Inclusive Care for the Elderly participants, and staff, and reflect on the lessons that were learned to date as a result of the COVID-19 PHE. The revisions to the requirements established COVID-19 vaccination requirements for staff at the included Medicare- and Medicaid-certified providers and suppliers.	42 CFR. § 416.51(c) 42 CFR. § 418.60(d) 42 CFR. § 441.151(c) 42 CFR. § 460.74(d) 42 CFR. § 482.42(g) 42 CFR. §483.80(d)(3)(v) and (d)(3)(i) 42 CFR. § 483.430(f) 42 CFR. § 483.460(a)(4) and (v) 42 CFR. § 484.70(d) 42 CFR. § 485.58(d)(4) 42 CFR. § 485.70(n) 42 CFR. § 485.640(f) 42 CFR. § 485.725(f) 42 CFR. § 485.904(c) 42 CFR. § 486.525(c) 42 CFR. § 491.8(d) 42 CFR. § 494.30(b) Regulation IFC 6: CMS–3415–IFC (86 FR 61555)

Appendix C. Medicare COVID-19 PHE Regulatory changes and Flexibilities: Testing, presented for purposes of illustration of what was in place during the time of the Pandemic and not necessarily reflective of the current time.

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations
April 6, 2020	**Medicare Clinical Laboratory Fee Schedule - Payment for Specimen Collection for Purposes of COVID-19 Testing.** CMS changed Medicare payment policies during the PHE to provide payment to independent laboratories for specimen collection and travel allowance for COVID-19 testing for homebound and non-hospital inpatients.	42 CFR part 414, subpart G Section 1833(h) of the Act IFC 1: CMS-1744-IFC (85 FR 19230)

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations
April 14, 2020	Increased payment for laboratory tests for the detection of SARS–COV–2 or the diagnosis of the virus that causes COVID–19 making use of high throughput technologies.	Section 1833(h) of the Act, Section 1834A of the Act, and 42 CFR part 414, subpart G. CMS Ruling [CMS-2020-01-R]
May 8, 2020	Hospital outpatient departments were paid for symptom assessment and specimen collection for COVID-19 using a new HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source) retroactive to March 1, 2020. The service was conditionally packaged and not paid separately when furnished with another payable service under the OPPS. This approach helped hospitals to operate testing sites during the PHE. When not billed with another separately payable hospital outpatient service, the national payment rate was roughly $23 for HCPCS code C9803.	Regulation IFC 2: CMS-5531-IFC (85 FR 27605)
May 8, 2020	**COVID-19 Diagnostic Testing.** CMS specified that the level one E/M visit (CPT code 99211), which can ordinarily be billed only when clinical staff perform services incident to the services of the billing physician or practitioner for an established patient, could be billed when clinical staff assessed a patient and collect a specimen for a COVID-19 diagnostic test for both new and established patients. After the PHE, the usual requirements for billing the level 1 E/M visit (CPT code 99211) apply.	Regulation IFC 2: CMS-5531-IFC (85 FR 19230)
May 8, 2020	**Modified Requirements for Ordering COVID-19 Diagnostic Laboratory Tests.** CMS implemented a policy to allow Medicare beneficiaries to get COVID-19 and other related testing during the COVID-19 PHE without requiring the order of the treating physician or practitioner, and instead allowing the testing to be ordered by any health care professional who is	IFC 2: CMS-5531-IFC (85 FR 27620 42 CFR § 410.32(a)

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations
	authorized to do so under applicable state law. This policy was further amended on September 2, 2020 as described below.	
May 8, 2020	**Antibody (serology) tests.** CMS permitted FDA-authorized COVID-19 serology testing to be a Medicare-covered diagnostic test for patients with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection.	IFC 2: CMS-5531-IFC (85 FR 27620) 42 CFR § 410.32(a)(3)
May 8, 2020	**Merit-Based Incentive Payment System (MIPS) Qualified Clinical Data Registry (QCDR) Measure Approval Criteria**. CMS amended the QCDR measure approval criteria previously finalized in the CY 2020 PFS final rule (84 FR 63065 through 63068), specifically: (1) Completion of QCDR measure testing at 42 CFR. § 414.1400(b)(3)(v)(C); and (2) collection of data on QCDR measures at 42 CFR. § 414.1400(b)(3)(v)(D).	IFC 2: CMS-5531-IFC (85 FR 19230) 42 CFR. § 414.1400(b)(3)(v)(C) and (D)
September 2, 2020	**Limits on COVID-19 and Related Testing without an Order and Expansion of Testing Order Authority.** CMS issued revised policy stating that each beneficiary could receive Medicare coverage for one COVID-19 test, and certain related tests, without the order of a physician or other health practitioner, but Medicare will require such an order to cover further COVID-19 and related tests. Medicare paid for tests when ordered by a pharmacist or other health care professional authorized under applicable state law to order diagnostic laboratory tests.	IFC 3: CMS-3401-IFC (85 FR 54871) 42 CFR. § 410.32(a)
September 2, 2020	**Revisions to Address CARES Act Enforcement Requirements for Hospitals and Laboratories.** CMS required all hospitals, CAHs, and laboratories performing testing related to COVID-19 and Acute Respiratory Illness, including Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection, to report information in accordance with a frequency, and in a standardized format, as specified by the Secretary during the PHE for COVID-19.	IFC 3: CMS-3401-IFC 42 CFR. § 493.2 42 CFR. § 493.41 42 CFR. § 493.555(c) 42 CFR. § 493.1100 42 CFR. § 493.1804 Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136)
September 2, 2020	**Established New Requirements for Long-Term Care Facilities to Conduct SARS-CoV-2 Testing for Staff and Residents.**	IFC 3: CMS-3401-IFC (85 FR 54873)

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations
	Under the new 483.80(h), CMS required LTC Facilities to test staff and residents. Specifically, facilities are required to test residents and staff, including individuals providing services under arrangement and volunteers, for COVID-19 based on parameters set forth by the Secretary. This rule enhanced efforts to keep COVID-19 from entering and spreading through LTC facilities. These regulations were applicable for the duration of the PHE for COVID-19. 42 CFR 488.447 was applicable 1 year beyond the expiration of the PHE for COVID-19.	42 CFR. § 483.80(h)
November 6, 2020	**Diagnostic Testing for COVID-19.** CMS encouraged private health plans to explore using payment arrangements that create incentives for providers to reduce the turnaround time to provide results for diagnostic testing for COVID-19.	Section 3202(a) of the CARES Act 6001 of the FFCRA IFC 4: CMS-9912-IFC (85 FR 71142)
November 6, 2020	**Price Transparency for COVID-19 Diagnostic Testing.** CMS implemented the CARES Act requirement that providers of a diagnostic test for COVID-19 make public the cash price for such tests on their websites for the duration of the PHE. Providers without their own websites were required to provide price information in writing within two business days upon request and on a sign posted prominently at the location where the provider performs the COVID-19 diagnostic test if such location is accessible to the public. Noncompliance could have resulted in civil monetary penalties up to $300 per day.	Section 3202(b) of the CARES Act IFC 4: CMS-9912-IFC (85 FR 71142) 45 CFR Part 182
January 1, 2021	Amended CMS Ruling to increase payment for laboratory tests for the detection of SARS–COV–2 or the diagnosis of the virus that causes COVID–19 making use of high throughput technologies.	Section 1833(h) of the Act, section 1834A of the Act 42 CFR part 414, subpart G. CMS Ruling [CMS-2020-01-R2]

Appendix D. Medicare and Medicaid COVID-19 PHE Waivers and Flexibilities: Telehealth. Presented for purposes of illustration of what was in place during the time of the Pandemic and not necessarily reflective of the current time.

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 1, 2020	Permitted a state Medicaid agency and clinic to temporarily designate a clinic practitioner's location as part of the clinic facility only to the extent necessary so that clinic services may be provided and reimbursed via telehealth when neither the patient nor practitioner is physically onsite at the clinic. Services provided via telehealth in clinic practitioners' homes (or another location) will be considered to be provided at the clinic (i.e., to meet the clinic services "facility requirement" at 42 CFR § 440.90(a)).	42 CFR. § 440.90(a)	
March 1, 2020	**Medicare Telehealth Practitioners.** CMS waived the requirements of section 1834(m)(4)(E) of the Act and 42 CFR. § 410.78 (b)(2), which specify the types of practitioners who may bill for their Medicare services when furnished via telehealth from a distant site. The waiver of these requirements expanded the types of health care professionals who can furnish distant site telehealth services to include all those who are eligible to bill Medicare for their professional services. As a result, a broader range of practitioners, such as physical therapists, occupational therapists, and speech language pathologists can use telehealth to provide many Medicare services.	42 CFR. § 410.78 (b)(2) Section 1834(m)(4)(E) of the Act; Section 302, CAA, 2022	

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 1, 2020	**Medicare Physician Services: Physician Visits.** CMS temporarily waived the requirement at 42 CFR. § 483.30(c)(3) that all required physician visits (not already exempted in 42 CFR. § 483.30(c)(4) and (f)) must be made by the physician personally. We modified this provision to permit physicians to delegate any required physician visit to a nurse practitioner, physician assistant, or clinical nurse specialist who is not an employee of the facility, who is working in collaboration with a physician, and who is licensed by the state and performing within the state's scope of practice laws. These actions assisted in preventing and addressing potential staffing shortages, maximizing the use of medical personnel, and protecting the health and safety of residents during the PHE. CMS did not waive the requirements for the frequency of required physician visits at 42 CFR. § 483.30(c)(1), and only modified the requirement to allow for the requirement to be met by a nurse practitioner, physician assistant, or clinical nurse specialist, and the requirement at 42 CFR. § 483.30 for physicians and nonphysician practitioners to perform in-person visits for LTC residents and allow visits to be conducted, as appropriate, via telehealth options. CMS did not waive requirements for physician supervision in 42 CFR. § 483.30(a)(1), or the requirement at 42 CFR. § 483.30(d)(3) for the facility to provide or arrange for the provision of physician services 24 hours a day, in case of an emergency.	42 CFR. § 483.30(c)(3) Section 1819(b)(6)(A) and (B) of the Act Section 1919(b)(6)(A) and (B) of the Act (Medicaid) Section 1135 Waiver (blanket Waiver)	

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 1, 2020	**Medicare Physician Visits in Skilled Nursing Facilities/Nursing Facilities.** CMS temporarily waived the requirement in 42 CFR. § 483.30 for physicians and non-physician practitioners to perform in-person visits for LTC residents, and allowed visits to be conducted, as appropriate, via telehealth options.	42 CFR. 483.30 Section 1819((b)(6)(A) and (B) of the Act (Medicare); 1919(b)(6)(A) and (B) of the Act (Medicaid) Section 1135 Waiver (blanket waiver)	
March 1, 2020	**Audio-Only Telehealth for Certain Medicare Services.** Pursuant to authority granted under the CARES Act, CMS waived the requirements of section 1834(m)(1) of the Act and 42 CFR. § 410.78(a)(3) for the use of interactive telecommunications systems to furnish services using telehealth to the extent they require use of video technology, for certain services. This waiver allows the use of audio-only equipment to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services. Unless provided otherwise, other services included on the Medicare Telehealth Services List must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. This flexibility was made permanent for mental and behavioral health services furnished via telehealth in the CY 2021 PFS.	42 CFR. § 410.78(a)(3) Section 1834(m)(1) of the Act; Section 3703 of CARES Act	

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 1, 2020	**Medicare Physician Supervision of Nurse Practitioners in RHCs and FQHCs.** CMS modified the requirement that physicians must provide medical direction for the clinic or center's health care activities and consultation for, and medical supervision of, the health care staff, only with respect to medical supervision of nurse practitioners, and only to the extent permitted by state law. The physician, either in person or through telehealth and other remote communications, continues to be responsible for providing medical direction for the clinic or center's health care activities and consultation for the health care staff, and medical supervision of the remaining health care staff. This allowed RHCs and FQHCs to use nurse practitioners to the fullest extent possible and allows physicians to direct their time to more critical tasks.	42 CFR. § 491.8(b)(1) Section 1135 Waiver (blanket waiver	This flexibility returned to pre-PHE rules at the end of the calendar year that the PHE ended.
March 1, 2020	**Medicare Practitioner Locations.** During the PHE, CMS waived the Medicare requirement that a physician or non-physician practitioner must be licensed in the state in which they are practicing if the physician or practitioner 1) is enrolled as such in the Medicare program, 2) has a valid license to practice in the state reflected in their Medicare enrollment, 3) is furnishing services – whether in person or via telehealth – in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity, and 4) is not affirmatively excluded from practice in the state or any other state that is part of the section 1135 emergency area.	42 CFR. § 482.22(a)(1)-(4) Section 1135 Waiver (blanket waiver)	

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 1, 2020	**Time Period for Initiation of Medicare Care Planning and Monthly Physician Visits.** CMS modified two requirements related to care planning, specifically: 42 CFR. § 494.90(b)(2): CMS modified the requirement which requires the dialysis facility to implement the initial plan of care within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This modification will also apply to the requirement for monthly or annual updates of the plan of care within 15 days of the completion of the additional patient assessments. 42 CFR. § 494.90(b)(4): CMS modified the requirement that the End-Stage Renal Disease (ESRD) dialysis facility ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. CMS has waived the requirement for a monthly in-person visit if the patient is considered stable and also recommends exercising telehealth flexibilities, e.g., phone calls, to ensure patient safety.	42 CFR. § 494.90(b)(2) 42 CFR. § 494.90(b)(4) Section 1881 (b)(3)(B)(i)) of the Act Section 1135 Waiver (blanket waiver)	

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 1, 2020	**Medicare Provider Enrollment – State Licensure Waivers.** CMS allowed licensed providers to render services outside of their state of enrollment when enrolled in Medicare, in possession of a valid license in the state of Medicare enrollment, furnishing services (either in person or via telehealth) to contribute to relief efforts in their professional capacity, and not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area. Also, CMS waived the board certification requirement for new physician assistants and nurse practitioners wherever states have likewise waived the requirement.	42 CFR. § 424.516(a)(2). 455.412 Section 1135 Waiver (blanket waiver)	

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 1, 2020	**Allowed Professionals working at RHCs and FQHCs to furnish Medicare telehealth services.** Section 3704 of the CARES Act authorizes RHCs and FQHCs to furnish distant site telehealth services to Medicare beneficiaries during the COVID-19 PHE. Medicare telehealth services generally require an interactive audio and video telecommunications system that permits real-time communication between the practitioner and the patient (although during the PHE, some telehealth services can be furnished using audio-only technology). CMS is allowing RHCs and FQHCs with this capability to provide and be paid for telehealth services furnished to Medicare patients located at any site, including the patient's home, through 2024, after the declared end of the COVID-19 PHE. Telehealth services can be furnished by any health care practitioner working for the RHC or the FQHC within their scope of practice. Practitioners can furnish telehealth services from any distant site location, including their home, during the time that they are working for the RHC or FQHC, and can furnish any telehealth service that is included on the list of Medicare telehealth services under the PFS), including those that are added on an interim basis during the PHE. A list of these services, including which can be furnished via audio-only technology, is available at: Medicare Telehealth Billing and Coding for fee-for-service Medicare claims.	1834(m)(8) of the Act Section 1135 Waiver (blanket waiver)	The CY 2022 Telehealth Update Medicare Physician Fee Schedule codified the continued coverage of video-based mental health visits for FQHCs and RHCs on a permanent basis.

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 31, 2020	**Site of Service for Medicare Telehealth Services.** For telehealth services furnished during the PHE, CMS allowed physicians and practitioners who bill for Medicare telehealth services to report the place of service code that would have been reported had the service been furnished in person. This allows CMS systems to make appropriate payment for services furnished via Medicare telehealth which, if not for the COVID-19 pandemic, would have been furnished in person, at the same rate they would have been paid if the services were furnished in person. To identify these services as Medicare telehealth, CMS is requiring that modifier 95 be appended to the claim.	Section 1834(m)(2)(B) of the Act Regulation IFC 1: CMS-1744-IFC CY 2023 PFS final rule (87 FR 69465) CY 2024 PFS Final Rule	CMS finalized in the CY 2024 PFS final rule that beginning in CY 2024, claims billed with place of service 10 be paid at the non-facility PFS rate, and claims billed with place of service 02 will continue to be paid at the facility rate.
March 31, 2020	**Adding Services to the Medicare Telehealth Services List.** CMS added many services temporarily, and some services permanently, to the Medicare Telehealth Services List. CMS also modified the process to add services to the Medicare Telehealth Services List during the PHE, allowing the agency to consider adding appropriate services on a sub-regulatory basis, as they are requested, as practitioners actively learn how to use telehealth.	42 CFR. § 410.78(f) Section 1834(m)(4)(F)(ii) of the Act Regulation IFC 1: CMS-1744-IFC CY 2023 PFS final rule with comment period CY 2024 PFS final rule	In the CY 2024 PFS final rule, CMS noted that it received several requests to permanently add various services to the Medicare Telehealth Services List effective for CY 2024. CMS found that none of the requests received by the February 10th submission deadline met the Category 1 or Category 2 criteria for permanent addition to the Medicare Telehealth Services List. CMS also finalized refinements to the process for considering requests to add services to the Medicare telehealth list.
March 6, 2020	**Allowed Medicare Telehealth Services regardless of Patient's Geographic Setting or Setting of Care.** CMS waived the geographic and site of service restrictions to allow beneficiaries, regardless of geographic or site of service location, to receive telehealth services anywhere in the U.S. .	Section 1834(m) of the Act, as amended by CAA, 2021 and Section 301, CAA, 2022 Regulation CY 2024 PFS final rule	CMS noted in the CY 2024 PFS final rule that following 2024, mental health telehealth services, as previously noted, as well as certain other services including ESRD-related services for home dialysis, will continue to be paid when furnished in the patient's home without geographic restrictions.

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 31, 2020	**Clarification of Technological Requirements for Medicare Telehealth.** CMS updated 42 CFR. § 410.78(a)(3) to recognize that an interactive telecommunications system for Medicare telehealth services can, under certain circumstances, include audio-only technology. CMS noted that the reference to "telephones" as outside the scope of interactive telecommunications technology could cause confusion in instances where otherwise eligible equipment, such as a smartphone, may also be used as a telephone. Because these concerns are not situation- or time-limited to the PHE for COVID-19, CMS finalized the removal of the second sentence of the regulation at 42 CFR. § 410.78(a)(3) that specified that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system. CMS also deleted the paragraphs at 42 CFR. § 410.78(a)(3)(i) and (ii). CMS noted that these amendments to the regulations would remove outdated references to specific types of technology and provide a clearer statement of the policy (85 FR 84531).	Section 1834(m) of the Act 42 CFR. § 410.78(a)(3) Regulation IFC 1: CMS-1744-IFC CY 2021 PFS final rule	This provision was made permanent in the CY21 PFS Final Rule.

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 31, 2020	**Removal of Frequency Limitations on Certain Medicare Telehealth Services.** CMS waived frequency restrictions for the following listed codes furnished via Medicare telehealth. A subsequent inpatient visit can be furnished via Medicare telehealth, without the limitation that the telehealth visit is provided a maximum of once every three days (CPT codes 99231- 99233). A subsequent skilled nursing facility visit can be furnished via Medicare telehealth, without the limitation that the telehealth visit is provided a maximum of once every 14 days (CPT codes 99307-99310). Critical care consult codes can be furnished to a Medicare beneficiary by telehealth beyond the once per day limitation (CPT codes G0508-G0509).	Regulation IFC 1: CMS-1744-IFC	In the CY 2025 Proposed PFS Rule, CMS proposes to continue to delay through December 31, 2025, before reinstating limitations on the number of times certain services in high-acuity settings may be performed via telehealth. During this time, CMS will continue to evaluate whether the removal of these frequency limitations should be made permanent.
March 31, 2020	**Level Selection for Office/Outpatient E/M Visits When Furnished Via Medicare Telehealth.** CMS specified that the office/outpatient E/M level selection for these services when furnished via telehealth can be based on Medical Decision Making or time, with time defined as all of the time associated with the E/M service on the day of the encounter; and removed requirements regarding documentation of history and/or physical exam in the medical record.	Section 1848(c) of the Act Regulation IFC 1: CMS-1744-IFC	This provision was made permanent in the CY21 PFS Final Rule.

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 31, 2020	**Telephone Evaluation, Management/Assessment and Management Services, and Behavioral Health and Education Services.** During the PHE, a broad range of clinicians were able to provide certain services by telephone to their patients. In the March 31st COVID-19 IFC (85 FR 19264 through 19265), CMS finalized separate payment for CPT codes 99441 through 99443 and 98966 through 98968, which describe E/M and assessment and management services furnished via telephone. CPT codes 99441 through 99443 are on the Medicare Telehealth Services List and will remain actively priced through 2024. CPT codes 98966 through 98968, however, describe telephone assessment and management services provided by a qualified non-physician health care professional, and they were added on a sub-regulatory basis during the PHE. CMS finalized the policy to continue to assign an active payment status to CPT codes 98966 through 98968 for CY 2024 to align with telehealth-related flexibilities that were extended via the CAA, 2023, specifically section 4113(e) of the CAA, 2023, which permits the provision of telehealth services through audio-only telecommunications through the end of 2024. The full Medicare Telehealth Services List notes which services are eligible to be furnished via audio-only technology, including the telephone evaluation and management visits: https://www.cms.gov/medicare/coverage/telehealth/list-services	42 CFR. § 410.78(a) Section 1834(m)(1) of the Act; Section 305 CAA, 2022 Regulation IFC 1: CMS-1744-IFC CY 2024 PFS final rule	

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 31, 2020	**Telehealth and the Medicare Hospice Face-to-Face Encounter Requirement.** CMS allowed the face-to-face encounter for purposes of patient recertification for the Medicare hospice benefit to now be conducted via telehealth (i.e., two-way audio-video telecommunications technology that allows for real-time interaction between the hospice physician/hospice nurse practitioner and the patient).	42 CFR. § 418.22(a)(4) 1814(a)(7)(D)(i) of the Act Regulation IFC 1: CMS-1744-IFC FY 2024 Hospice Final Rule	In the FY 2024 hospice final rule, CMS finalized that the face-to-face encounter may be performed via telecommunications technology during a PHE, as defined in 42 C.FR § 400.200, or through December 31, 2024, whichever is later.
March 31, 2020	**Required "Hands-On" Visits for ESRD Monthly Capitation Payments.** For all patients of Medicare-certified ESRD facilities, CMS exercised enforcement discretion and removed the requirement that clinicians must have one "hands-on" visit per month without the use of telehealth for services furnished during the PHE.	42 CFR. § 494.80(b)(1) Sections 1881(b)(3) and 1834(m) of the Act Regulation IFC 1: CMS-1744-IFC	
March 31, 2020	**HHA Medicare Telehealth and Telecommunications Technology.** CMS allowed HHAs to provide more services to beneficiaries using telecommunications technology within the 30-day period of care, as long as it's part of the patient's plan of care and does not replace needed in-person visits as ordered on the plan of care. CMS acknowledged that the use of such technology may result in changes to the frequency or types of in-persons visits outlined on existing or new plans of care. Telecommunications technology can include, for example: remote patient monitoring; telephone calls (audio-only and teletypewriters (TTY)); and two-way audio-video technology that allows for real-time interaction between the clinician and patient. However, only in-person visits can be reported on the home health claim.	42 CFR. § 409.43(a) Section 1895 of the Act Regulation IFC 1: CMS-1744-IFC	This provision was made permanent in the CY21 HH PPS Final Rule.

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 31, 2020	**HHA Medicare Telehealth and Telecommunications Technology.** CMS allowed the required face-to-face encounter for home health to be conducted via telehealth (i.e., two-way audio-video telecommunications technology that allows for real-time interaction between the physician/allowed practitioner and the patient) when the patient is at home. The face-to-face encounter can be conducted via telehealth irrespective of the COVID-19 PHE; however, the waiver only extends the "originating site" to the patient's home to 151 days past the end of the COVID-19 PHE.	42 CFR. § 410.78(b)(3) Section 1834(m) of the Regulation IFC 1: CMS-1744-IFC Act	
March 31, 2020	**Hospice Medicare Telehealth and Telecommunications Technology.** CMS allowed hospice providers to provide services to a Medicare patient receiving routine home care through telecommunications technology (e.g., remote patient monitoring; telephone calls (audio-only and TTY); and two-way audio-video technology), if it is feasible and appropriate to do so. Only in-person visits are to be recorded on the hospice claim.	42 CFR. § 418.204 Section 1814(a)(7)(B) of the Act Regulation IFC 1: CMS-1744-IFC FY 2024 Hospice Final Rule	In the FY 2024 hospice final rule, CMS finalized to remove 42 CFR. § 418.204(d), effective retroactively to May 12, 2023, to align with the end of the COVID–19 PHE. That is, effective May 12, 2023, routine home care hospice services can no longer be furnished using telecommunications technology.

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 31, 2020	**Medicare Application of Certain National Coverage Determination and Local Coverage Determination Requirements During the PHE for the COVID-19 Pandemic.** CMS modified certain National coverage determinations (NCDs) and Local coverage determinations (LCDS), including: To the extent that a NCD or LCD would otherwise require an in-person, face-to-face visit for evaluations and assessments, CMS used section 1135 waiver authority to remove those requirements so that these services can be furnished via telehealth during the PHE. To the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish or supervise a service, during the PHE, the Chief Medical Officer or equivalent of a hospital or facility has had the authority to make those staffing decisions. CMS has not enforced clinical restrictions in certain NCDs and LCDs that otherwise would have restricted coverage of Respiratory Related Devices, Oxygen and Oxygen Equipment, Home Infusion Pumps and Home Anticoagulation Therapy devices and services for COVID-19 patients during the PHE. Clinicians have had more flexibility in determining patient needs for respiratory related devices and equipment and the flexibility for more patients to manage their treatments at home but need to continue to document those decisions in the medical record.	42 CFR. § 410.38 Section 1862(a)(1)(A) of the Act Regulation IFC 1: CMS-1744-IFC	

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 31, 2020	**Modification of the Medicare Inpatient Rehabilitation Facility (IRF) Face-to-Face Requirement for the PHE During the COVID-19 Pandemic.** CMS permitted the face-to-face visit requirements at 42 CFR. § 412.622(a)(3)(iv) and 412.29(e) to be conducted via telehealth to safeguard the health and safety of Medicare beneficiaries and the rehabilitation physicians treating them. This allows rehabilitation physicians to use telehealth services as defined in section 1834(m)(4)(F) of the Act, to conduct the required three physician visits per week during the PHE for the COVID-19 pandemic.	42 CFR. § 412.622(a)(3)(iv) 42 CFR. § 412.29(e) Section 1886(j) of the Act Regulation IFC 1: CMS-1744-IFC	The flexibility allowed for the use of telehealth services for conducting the IRF face-to-face visit requirements terminated at the end of the Covid-19 PHE on May 11, 2023.
May 8, 2020	**Medicare Telehealth.** During the PHE, telehealth was used to fulfill the requirement for physicians to conduct the required face-to-face visits at least three days a week for the duration of a Medicare Part A fee-for-service patient's stay in an inpatient rehabilitation facility.	42 CFR. § 412.29 Section 1834(m)(4)(F) of the Act Regulation IFC 2: CMS-5531-IFC	

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
May 8, 2020	**Additional Medicare Flexibility under the Teaching Physician Regulations.** Under current rules, Medicare payment is made for services furnished by a teaching physician involving residents only if the physician is physically present for the key portion of the service or procedure, and immediately available to furnish services during the entire procedure, where applicable. During the COVID-19 PHE, teaching physicians were able to use audio/video real-time communications technology to interact with the resident through virtual means, which would meet the requirement that they be present for the key portion of the service, including when the teaching physician involves the resident in furnishing Medicare telehealth services. CMS announced in the CY 2024 Physician Fee Schedule final rule (88 FR 78881) that it is exercising enforcement discretion to allow teaching physicians in all residency training sites to be present through audio/video real-time communications technology, for purposes of billing under the PFS for services they furnish involving residents through December 31, 2023.	42 CFR. § 415.172 Regulation IFC 2: CMS-5531-IFC CY 2024 PFS final rule	After the PHE, only teaching physicians in residency training sites located outside of a metropolitan statistical area may meet the presence for the key portion requirement through audio/video real-time communications technology. These flexibilities do not apply in the case of surgical, high-risk, interventional, or other complex procedures, services performed through an endoscope, and anesthesia services. In the CY 2024 PFS final rule, CMS finalized the policy to allow teaching physicians to have a virtual presence in all teaching settings, only in clinical instances when the service is furnished virtually. This permits teaching physicians to have a virtual presence during the key portion of the virtual service for which payment is sought, through audio/video real-time communications technology, for all residency training locations through December 31, 2024. As finalized in the CY 2021 PFS final rule (84577 through 84581), the required physical presence of a teaching physician in order to bill under the PFS for their services at a residency training site that is located outside of a metropolitan statistical area (MSA) can be met through interactive, audio/video real-time communications technology, and does not include audio-only technology. This allows teaching hospitals to maximize their workforce to safely take care of patients.

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
May 8, 2020	**Furnishing Medicare Outpatient Services in Temporary Expansion Locations: Hospital.** CMS clarified that hospitals could furnish clinical staff services (for example, drug administration) in the patient's home, and to bill and be paid for these services when the patient is registered as a hospital outpatient. Further, CMS clarified that when a patient is receiving a professional service via telehealth in a location that is considered a hospital provider-based department, the hospital in which the patient is registered may bill the originating site facility fee for the service. Finally, CMS clarified the applicability of section 603 of the Bipartisan Budget Act of 2015 to hospitals furnishing care in the beneficiaries' homes (or other temporary expansion locations), and whether those locations are considered relocated, partially relocated, or new provider-based departments.	42 CFR. § 410.27 Section 1834(m) of the Act Regulation IFC 2: CMS-5531-IFC	

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
May 8, 2020	**Furnishing Medicare Outpatient Services in Temporary Expansion Locations of a Community Mental Health Center (Including the Patient's Home).** For the duration of the COVID-19 PHE, CMS waived the restriction at 42 CFR. § 485.918(b)(1)(iii) for the purpose of providing PHP services to CMHC patients in their homes, which will be considered a temporary expansion location of a CMHC. A temporary expansion location where the beneficiary may be located, including the beneficiary's home, can be considered part of a CMHC, and certain therapeutic services furnished to beneficiaries, when the beneficiary is registered as an outpatient of the CMHC, in these temporary expansion locations can meet the requirement that these services be furnished in the CMHC. Specifically, for the purposes of the COVID-19 PHE and effective as of March 1, 2020, CMS considered temporary expansion locations where the beneficiary may be located, including a beneficiary's home, to be a part of the CMHC once a patient is registered as an outpatient of the CMHC, while PHP services are being furnished at that location by CMHC staff in accordance with the supervising practitioner's scope of practice. Therefore, CMS considered services furnished in that location to have been furnished in the CMHC. The CMHC should bill for these services as if they were furnished in the CMHC and consistent with any specific requirements for billing Medicare during the COVID-19 PHE.	42 CFR. § 410.27; 42 CFR. § 413.65. 42 CFR. § 485.918(b)(1)(iii) Section 1861(ff)(3)(A) of the Act 1135 Blanket Waiver	

Effective Date	Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
January 1, 2020	**Changes to Medicare Shared Savings Program—Beneficiary Assignment Methodology**. CMS used an expanded definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication.	42 CFR. § 425.400(c)(2) 42 CFR. § 425.400(c)(1)(v) 42 CFR. § 425.400(c)(1)(vi) Section 1899 of the Act. Refer to IFC 2 (85 FR 27551, 275–2 - 27586), CY 2021 PFS final rule (85 FR 847–7 - 84755, 847–5 - 84793); CY 2022 PFS final rule (86 FR 652–4 - 65276). The regulations in 42 CFR. § 425.400(c)(2) were effective May 8, 2020 (85 FR 27550). 42 CFR. § 425.400(c)(2), as revised, was applicable retroactively for the performance year starting on January 1, 2020 (85 FR 27551, 85 FR 84472).	

Appendix E. Medicare COVID-19 PHE Waivers and Flexibilities: LTC Facilities. Presented for purposes of illustration of what was in place during the time of the Pandemic and not necessarily reflective of the current time.

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
March 1, 2020	**Provider Enrollment –Waive Application Fees.** CMS temporarily waived the collection of application fees for institutional providers who were initially enrolling, revalidating, or adding a new practice location. Only institutional providers are generally required to submit application fees under current regulation. Institutional providers include entities such as hospitals, SNFs, and independent clinical laboratories. See Application Fee requirements for Institutional Providers (cms.gov).	42 CFR. § 424.514	CMS has resumed collecting application fees.
March 1, 2020	**In-Service Training for LTC Facilities.** CMS temporarily waived the nurse aide training requirements at 42 CFR. § 483.95(g)(1) for SNFs and NFs, which require the nursing assistant to receive at least 12 hours of in-service training annually. In accordance with section 1135(b)(5) of the Act, CMS postponed the deadline for completing this requirement. Nurse aides hired prior to and under the current waiver (on or before June 6, 2022) will have 12 months from this date to complete the required annual training.	42 CFR. § 483.95(g)(1) Section 1819(b)(5)(E) of the Act	QSO-22-15-NH, issued April 7, 2022, terminated this waiver on June 7, 2022.
March 1, 2020	**LTC Facility -- Training and Certification of Nurse Aides.** CMS temporarily waived the requirements at 42 CFR. § 483.35(d), (except for 42 CFR. § 483.35(d)(1)(i)), which require that a SNF and NF may not employ anyone for longer than four months unless they meet the training and certification requirements under 42 CFR. § 483.35(d). CMS waived these requirements to assist in potential staffing shortages seen with the COVID-19 pandemic. To ensure the health and safety of LTC residents, CMS did not waive 42 CFR. § 483.35(d)(1)(i), which requires facilities to not use any individual working as a nurse aide for	42 CFR. § 483.35(d) Section 1819(5)(A)(i) (I) (II) of the Act 1135 Waiver	The QSO-22-15-NH, issued April 7, 2022, terminated this waiver. Individual waivers ended with issuance of QSO-23-13-ALL.

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
	more than four months, on a full-time basis, unless that individual is competent to provide nursing and nursing-related services. In addition, CMS did not waive 42 CFR. § 483.35(c), which requires facilities to ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care. This waiver was "conditionally terminated." Facilities that experienced barriers to nurse aide certification worked under a waiver, per QSO-22–5--NH & NLTC & LSC. Nurse aides hired under the waiver (on or before June 6, 2022) had until October 6, 2022, to complete a Nurse Aide Training and Competency Evaluation Program (NATCEP).		
March 1, 2020	**LTC facility -- Physician Services: Physician Visits.** CMS temporarily waived the requirement at 42 CFR. § 483.30(c)(3) that all required physician visits (not already exempted in 42 CFR. § 483.30(c)(4) and (f)) must be made by the physician personally. We modified this provision to permit physicians to delegate any required physician visit to a nurse practitioner, physician assistant, or clinical nurse specialist who is not an employee of the facility, who is working in collaboration with a physician, and who is licensed by the state and performing within the state's scope of practice laws. These actions assisted in preventing and addressing potential staffing shortages, maximizing the use of medical personnel, and protecting the health and safety of residents during the PHE. CMS did not waive the requirements for the frequency of required physician visits at 42 CFR § 483.30(c)(1), and only modified the requirement to allow for the requirement to be met by a nurse practitioner, physician assistant, or	42 CFR. § 483.30(c)(3) Section 1819(6)(A) and (B) of the Act	QSO-22-15-NH, issued on April 7, 2022, terminated this waiver on May 7, 2022.

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
	clinical nurse specialist, and the requirement at 42 CFR. § 483.30 for physicians and nonphysician practitioners to perform in-person visits for LTC residents and allow visits to be conducted, as appropriate, via telehealth options. CMS did not waive requirements for physician supervision in 42 CFR. § 483.30(a)(1), or the requirement at 42 CFR. § 483.30(d)(3) for the facility to provide or arrange for the provision of physician services 24 hours a day, in case of an emergency.		
March 1, 2020	**Physician Visits in Skilled Nursing Facilities/Nursing Facilities.** CMS temporarily waived the requirement in 42 CFR. § 483.30 for physicians and non-physician practitioners to perform in-person visits for LTC residents, and allowed visits to be conducted, as appropriate, via telehealth options.	42 CFR 483.30 § Section 1819(6)(A)(B) of the Act	QSO-22-15-NH, issued on April 7, 2022, terminated this waiver on May 7, 2022.
March 1, 2020	**Waive Pre-Admission Screening and Annual Resident Review (PASARR)**. CMS waived 42 CFR. § 483.20(k), allowing LTC facilities to admit new residents who have not received Level 1 or Level 2 Preadmission Screening. Level 1 assessments may be performed post-admission. On or before the 30th day of admission, new patients admitted to LTC facilities with a mental illness (MI), or intellectual disability (ID) were referred by the facility to the State PASARR program for Level 2 Resident Review.	42 CFR. § 483.20(k) Section1819(b)(3)(E) of the Act	QSO-23-13-ALL, issued May 1, 2023, terminated this waiver immediately with the expiration of the COVID-19 PHE.
March 1, 2020	**Expanding Availability of Renal Dialysis Services to ESRD Patients.** CMS waived ESRD requirements at 42 CFR. § 494.180(d) that require dialysis facilities to provide services directly on their main premises or on other premises that are contiguous with the main premises. CMS allowed dialysis facilities to provide services to its patients in LTC facilities, assisted living facilities, and similar types of facilities, as licensed by the state (if applicable). CMS continues to require that services provided to these patients or residents	42 CFR. § 494.180(d)	1135 Waiver (blanket waiver)

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
	are under the direction of the same governing body and professional staff as the resident's usual Medicare-certified dialysis facility. Further, in order to ensure that care is safe, effective and is provided by trained and qualified personnel, CMS requires that the dialysis facility staff furnish all dialysis care and services; provide all equipment and supplies necessary; maintain equipment and supplies in the off-premises location; and complete all equipment maintenance, cleaning and disinfection using appropriate infection control procedures and manufacturer's instructions for use.		
May 8, 2020	**LTC Facilities -- Required Facility Reporting.** Under 42 CFR. § 483.80(g), long-term care facilities were required to report information on COVID-19 cases in their facility to the CDC National Health Safety Network on a weekly basis. CDC and CMS used information collected through the new National Healthcare Safety Network LTC COVID-19 Module to strengthen COVID-19 surveillance locally and nationally; monitor trends in infection rates; and help local, state, and federal health authorities get help to LTC facilities faster. The information was also be posted online for the public to be aware of how the COVID-19 pandemic is affecting LTC facilities. In COVID-19 PHE Interim Final Rule #3 (CMS-3401-IFC), CMS codified enforcement actions for facilities' noncompliance with this reporting requirement. Failure to report resulted in the imposition of a civil money penalty for each occurrence of non-reporting as follows: A civil money penalty of $1,000 for the first occurrence, followed by $500 added to the previously imposed civil money penalty for each subsequent occurrence, not to exceed the maximum amount set forth in 42 CFR. § 488.408(d)(1)(iii). Facilities were also required to notify residents, their representatives, and	42 CFR. § 483.80(g) 42 U.S.C. 1302, 1320a-7, 1395i, 1395hh and 1396r. Regulation IFC 2: CMS-5531-IFC	The 2022 CY Home Health PPS Rule extended this mandatory COVID-19 reporting requirement beyond the current COVID-19 PHE until December 31, 2024.

Effective Date	Regulation/Waiver/Flexibility Description	Relevant Authorities/ Citations	Post-PHE Action(s)
	families of residents in facilities of the status of COVID-19 in the facility, which includes any new cases of COVID-19 as they are identified. This action supports CMS' commitment to transparency so that individuals know important information about their environment, or the environment of a loved one.		

Appendix F. Medicaid Section 1135 Waivers and Flexibilities. Presented for purposes of illustration of what was in place during the time of the Pandemic and not necessarily reflective of the current time.

Effective Date	Description of Section 1135 Waiver Policy	States and Territories with Approved Section 1135 Waiver
March 1, 2020	Temporarily suspended State Plan Medicaid fee-for-service prior authorization requirements for benefits. Prior authorization and medical necessity processes in fee-for-service delivery systems are established, defined, and administered at state discretion and may vary on the benefit. With this 1135 waiver, states may elect to temporarily suspend these processes, as needed, during the PHE.	AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, KS, KY, ME, MD, MA, MI, MN, MS, MO, MT, NE, NH, NJ, NM, NY, NC, ND, MP, OH, OK, OR, PA, RI, VI, UT, VT, VA, WA, WV, WI, WY (45 total)
March 1, 2020	Extended pre-existing authorizations for which a beneficiary has previously received prior authorization through the end of the PHE. Prior authorization and medical necessity processes in fee-for-service delivery systems are generally established, defined, and administered at state discretion and may vary on the benefit. With this 1135 waiver, states may elect to extend prior authorizations for services, as needed, during the PHE.	AL, AK, AZ, CA, CO, CT, DE, DC, FL, GA, ID, IL, IN, KS, LA, ME, MD, MA, MI, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, MP, OR, PA, RI, SC, TX, VI, VT, VA, WA, WV, WI (42 total)
March 1, 2020	Delayed PASRR Level I and Level II Assessments for 30 days from the date of each individual's admission.	AL, AK, AZ, AR, CO, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, VI, UT, VT, VA, WA, WV, WI, WY (49 total)
March 1, 2020	Temporarily extended the timeframes for individuals to request Medicaid fair hearings in fee-for-service. This 1135 waiver allowed applicants and beneficiaries to have more than 90 days to request a fair hearing for eligibility or fee-for-service appeals by extending the timeframe in 42 CFR. § 431.221(d), which requires states to choose a reasonable timeframe for eligibility or fee-for-service appeals.	AK, AR, CA, CO, CT, DE, DC, FL, GA, HI, IL, IN, KS, KY, LA, ME, MD, MA, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, MP, OK, OR, PA, PR, RI, SC, SD, TX, VI, UT, VT, VA, WA, WV, WY (46 total)
March 1, 2020	Temporarily extended the timeframes for individuals to request Medicaid fair hearings in managed care. States modified timeframes to give enrollees more than 120 days to request a state fair hearing and modify the timeframe for managed care plans to resolve appeals to no less than one day, allowing managed care enrollees to proceed almost immediately to a state fair hearing.	AR, CA, CO, DE, DC, FL, GA, HI, IL, IN, KS, KY, LA, MD, MA, MN, MS, MO, NV, NH, NJ, NM, NY, NC, ND, OK*, OR, PA, PR, RI, SD*, TX, UT, VT, VA, WA, WV (37 total) **OK and SD made a general request for section 1135 fair hearings flexibilities and did not specify fee-for-service or managed care. The CMS approval letters for SD and OK include both FFS and managed care*

Effective Date	Description of Section 1135 Waiver Policy	States and Territories with Approved Section 1135 Waiver
		flexibilities, although these states currently do not have managed care organizations.
March 1, 2020	Allowed states to provisionally, temporarily enroll providers who are enrolled with another state Medicaid agency or with Medicare for the duration of the PHE. With respect to providers not already enrolled with another state Medicaid agency or Medicare, waived certain screening requirements (payment of the application fee, criminal background checks, site visits, and in-state/territory licensure requirements) to temporarily enroll providers for the PHE. Also permitted states to temporarily cease provider revalidation. States had to adhere to the minimum requirements outlined in the approval letter.	AL, AK, AS, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, MP, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, VI, UT, VT, VA, WA, WV, WI, WY (55 total)
March 1, 2020	Allowed facilities, including NFs, intermediate care facilities for individuals with intellectual and developmental disabilities (ICF/IDDs), psychiatric residential treatment facilities, and hospital NFs, to be fully reimbursed for services rendered to an unlicensed facility (during an emergency evacuation or due to other need to relocate residents where the placing facility continues to render services) provided that the state makes a reasonable assessment that the facility meets minimum standards to ensure the health, safety and comfort of beneficiaries and staff (consistent with reasonable expectations in the context of the PHE).	AK, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, MP, OH, OK, OR, PA, RI, SC, SD, TN, UT, VT, VA, WA, WV, WI, WY (46 total)
March 1, 2020	Allowed the state to modify the deadline for the initial and annual level of care determinations required for the 1915(k)-state plan benefit. With this waiver, the initial determination of level of care did not need to be completed before the start of services, and annual level of care determinations that exceed the 12-month authorization period will remain in place and services will continue until the assessment can occur. Reassessments could've been postponed for up to one year.	AK, CT, MT, OR, TX (5 total)

Effective Date	Description of Section 1135 Waiver Policy	States and Territories with Approved Section 1135 Waiver
March 1, 2020	Allowed the state to modify the regulatory eligibility and assessment of need timelines associated with the 1915(i)-state plan benefit. With this waiver, these activities did not need to be completed before the start of care. Also allowed the state to modify the deadline for annual redetermination of eligibility and reassessment of need. With these waivers, the annual eligibility determinations, and reassessments of need that exceed the 12-month authorization period will remain in place and services will continue until the re-evaluation and reassessment can occur. These actions could've been postponed for up to one year.	AR, CT, DC, IA, OR, TX (6 total)
March 1, 2020	Permitted the state to modify the deadline for initial and annual level of care determinations required for section 1915(c) HCBS waiver programs. With this 1135 waiver, the initial determination of level of care did not need to be completed before the start of services, and annual level of care determinations that exceed the 12-month authorization period will remain in place and services will continue until the assessment can occur. Reassessments could've been postponed for up to one year.	CO, LA, MN, NJ, NY, NC, OH, TX (8 total)
March 1, 2020	Temporarily allowed payment for 1905(a) personal care services rendered by legally responsible individuals (which could be inclusive of legally responsible family caregivers) provided that the state makes a reasonable assessment that the caregiver is capable of rendering such services. This waiver helped to ensure medically necessary services are furnished in the event the traditional provider workforce is diminished or there is inadequate capacity due to the PHE.	AK, GA, ID, IA, LA, MD, MN, MT, NH, NJ, NM, ND, OK, PA, VT (15 total)
March 1, 2020	Temporarily allowed HCBS provided under section 1915(c), 1915(i), and 1915(k) authorities, and section 1115 demonstrations, to be provided in settings that have not been determined to meet the home and community-based settings criteria set forth in Medicaid regulations (e.g., 42 CFR. § 441.301(c)(4) applicable to section 1915(c) waiver programs). This waiver applied to settings that have been added since the March 17, 2014 effective date of the HCBS final rule (79 FR 2948), to which the HCBS settings criteria currently apply, in order to accommodate circumstances in which an individual requires relocation to an alternative setting to ensure the continuation of needed HCBS.	AK, AZ, CA, CT, DC, IN, ME, MD, MA, MI, MN, MO, MT, NH, NJ, NY, OH, OR, PA, RI, SC, TN, TX, UT, VT, WA, WV, WI (28 total)

Effective Date	Description of Section 1135 Waiver Policy	States and Territories with Approved Section 1135 Waiver
March 1, 2020	Permitted the state to temporarily authorize reimbursement for HCBS provided by an entity that also provides case management services and/or is responsible for the development of the person-centered service plan (typically not permitted due to conflict of interest). By permitting the entity rendering case management to also render HCBS directly, this allowed for the expansion of service providers when it is necessary to increase the provider pool during the PHE.	AZ, MN, MT, NY, NC, OR, UT, WA (8 total)
March 1, 2020	Allowed the state to waive or modify the requirement to obtain beneficiary and provider signatures on HCBS person-centered service plans, allowing states to permit documented verbal consent as an alternate to the regulatory requirement for a signature on the person-centered service plans from beneficiaries and all providers responsible for its implementation.	AK, AZ, AR, CA, CO, CT, DC, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NJ, NY, ND, OH, OK, OR, PA, TX, UT, VT, WA, WV, WI, WY (32 total)
March 1, 2020	Allowed the state to modify the deadline for the face-to-face encounter required for home health services. With this waiver, the face-to-face encounter did not need to be completed before the start of services and may occur at the earliest time, not to exceed 12 months from the start of service.	AK, AZ, CT, LA, MO, NH, NY, NC, OR, PA, SC, UT, WA (13 total)
March 1, 2020	Temporarily allowed payment for 1915(k) attendant services and supports rendered by an individual's representative provided that the state makes a reasonable assessment that the caregiver is capable of rendering such services. This waiver helped to ensure that medically necessary services are furnished in the event the traditional provider workforce is diminished or there is inadequate capacity due to the PHE.	AK, OR (2 total)
March 1, 2020	Modified the deadline for conducting an annual targeted case management services monitoring visit. With this waiver, the timeframe for completion of the annual monitoring activity could've been postponed up to one year.	MD, MA, MO, MT (4 total)
March 1, 2020	Modified timelines for managed care authorization decisions to allow two possible extensions up to 90 days each to allow the managed care plan more time to collect additional information needed to make an authorization decision that is favorable to the enrollee. Modified timeframes to file an appeal from 60 to 120 days following the receipt of an adverse benefit determination to allow more time for the enrollee to file a request for an internal appeal with the managed care plan. Modified timeframe for standard appeals from 14 days to 30 days to allow the managed care plan additional time to obtain necessary information,	NY, TX (2 total)

Effective Date	Description of Section 1135 Waiver Policy	States and Territories with Approved Section 1135 Waiver
	if the delay is in the enrollee's interest, such as to gather information necessary for a decision that is favorable to the enrollee.	
March 1, 2020	Allowed private duty nursing services to be delivered by a graduate registered nurse and/or graduate licensed practical nurse. This flexibility allowed the state to reimburse for services delivered by these providers whose practice is consistent with the functions of and requirements for registered nurses and licensed practical nurses, but who do not yet have the title "Registered Nurse" or "Licensed Practical Nurse."	MO, OR (2 total)
March 1, 2020	Permitted the state and clinic to temporarily designate a clinic practitioner's location as part of the clinic facility only to the extent necessary so that states could pay for clinic services provided via telehealth when neither the patient nor practitioner is physically onsite at the clinic. Services provided *via telehealth* when the clinic practitioner is in their home (or another location) were considered to be provided at the clinic (i.e., meet the clinic services facility requirement" at 42 CFR § 440.90(a)).	AK, CA, CT, ME, MD, MI, MO, NY, NC, SD, TN, VT (12 total)
March 1, 2020	Allowed the state to modify the assessment and service plan timeframes associated with the 1915(j) Self- Directed PA) Program state plan benefit. The state could've modified the timeframes for conducting the assessments to make a determination that an individual requires PAS and supports, and for development of the service plan and budget. These activities did not need to be completed before the start of care. The state could've also modified the deadline for annual review of the service plan, enabling services to continue until the annual review can occur. These actions could've been postponed for up to one year.	OR (1 total)
March 1, 2020	Allowed the state to modify the deadlines for conducting functional need initial assessments and reassessments, and the annual review of person-centered service plans for the 1915(k) Community First Choice state plan benefit. With this waiver, the initial assessment of functional need was not required to be completed before the start of care.	MT, OR (2 total)
March 1, 2020	Allowed provision of clinic services within scope without the direction of a physician or a dentist when provided by other licensed professionals.	PA (1 total)
March 1, 2020	Allowed the provision of inpatient psychiatric services within scope for individuals under age 21 without the direction of a physician during the PHE.	NY, PA (2 total)

Effective Date	Description of Section 1135 Waiver Policy	States and Territories with Approved Section 1135 Waiver
March 1, 2020	Modified supervision requirements to allow private duty nursing services to be directed by a nurse practitioner, clinical nurse specialist, and/or physician assistant; allows states to reimburse for private duty nursing services provided by qualified providers under the direction of nurse practitioners, clinical nurse specialists, and/or physician assistants during the COVID-19 PHE.	MA (1 total)
March 1, 2020	Allowed the state to extend the regulatory timeframe to reinstate services and benefits for beneficiaries who request a fair hearing more than 10 days after the date of action (per federal regulations, states have the option to reinstate services if a beneficiary requests a fair hearing not more than 10 days after the date of action/termination). Under this waiver, the timeframe could not exceed the time permitted for beneficiaries to request a fair hearing (under either the state plan or under an approved section 1135 waiver) and the state should reinstate the individual's services and benefits as quickly as practicable.	AK, CA, KY, NV, NC, RI, TX, VT, VA (9 total)
March 1, 2020	Permitted modification of timeframes to allow the Medicaid managed care plan to continue benefits if requested within the current 10-day timeframe or reinstate benefits for the enrollee when the individual requests continuation of benefits between 11 and 30 days if the managed care plan had not yet made a decision on the appeal or the state fair hearing is pending.	CA, KY, NV, NC, RI, TX, VT, VA (8 total)
Date varies by individual SPA; No earlier than March 1, 2020	Modified SPA submission requirement that a SPA must be submitted by the last day of a quarter in order to take effect in that quarter. This waiver allowed states to have an earlier SPA effective date.	AK, AL, AR, AS, AZ, CA, CO, CNMI, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MS, MO, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OK, OH, OR, PA, PR, RI, SC, SD, TX, TN, UT, VA, VI, VT, WA, WI, WV, WY (53 total)
Date varies by individual SPA; No earlier than March 1, 2020	Permitted a waiver or modification of applicable requirements to provide public notice prior to the submission of certain types of SPAs.	AK, AL, AR, AZ, CA, CNMI, CO, CT, DC, DE, FL, GA, GU, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MS, MO, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OK, OH, OR, PA, PR, RI, SC, SD, TX, UT, VA, VI, VT, WA, WI, WV, WY (55 total)

Effective Date	Description of Section 1135 Waiver Policy	States and Territories with Approved Section 1135 Waiver
Date varies by individual SPA; No earlier than March 1, 2020	Allowed modification of the time frames associated with tribal consultation regarding a SPA. These section 1135 approvals did not waive the requirement to conduct tribal consultation but did permit modification of the timeframes for tribal consultation; for example, to permit the state to conduct consultation after SPA submission.	AK, AL, AZ, CA, CO, CT, FL, HI, IA, ID, IL, KS, LA, MA, ME, MI, MN, MS, MO, MT, NC, ND, NE, NM, NV, NY, OK, OR, RI, SD, TX, UT, VA, WA, WI, WY (36 total)

Appendix G. Legislation Enacted

Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123). On March 4, 2020, the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (H.R. 6074) was introduced and passed by the House the same day.[166] The bill was passed by the Senate the following day, on March 5, and signed into law (P.L. 116-123) on March 6.[167] This was the first law enacted in response to the COVID-19 outbreak. The funds in Division A of this law focused on preventing, preparing for, and responding to the coronavirus.[168] Division A included supplemental appropriations to various agencies such as the FDA, CDC, and the National Institutes of Health. Division B, Telehealth Services During Certain Emergency Periods Act of 2020, amended the Secretary's authority regarding Medicare telehealth services.[169] The law granted the HHS Secretary authority to temporarily waive or modify application of certain Medicare requirements with respect to Medicare services delivered using telehealth provided during certain emergency periods.[170]

Families First Coronavirus Response Act (FFCRA) (P.L. 116-127). On March 18, 2020, a second law, the FFCRA, was enacted in response to the COVID-19 outbreak.[171] The FFCRA provided additional funding to the Department of Defense, Indian Health Service, HHS, and Veterans Health Administration for testing and ancillary services associated with COVID-19.[172] Division F, Health Provisions, included coverage of COVID-19 testing for health insurance issuers offering group and individual plans, and coverage of COVID-19 testing with no cost-sharing under Medicare, Medicaid, and CHIP. The law also included clarification regarding the HHS Secretary's authority related to Medicare services delivered using telehealth during the PHE, and a temporary increase in the FMAP. The law also established the optional COVID-19 Medicaid eligibility group with a limited benefit package covering COVID-19 testing and testing-related services, and an increase in Medicaid allotments for territories, among other provisions.[173]

The Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136). The CARES Act was enacted on March 27, 2020, and provided over $2 trillion to assist businesses, federal agencies, state and local governments, and industry sectors impacted by the COVID-19 PHE. [174, 175] Subtitle A in title III of the CARES Act contained health provisions, which included coverage of COVID-19 testing, pricing of diagnostic testing, rapid coverage of preventive services and vaccines for coronavirus, and telehealth network and telehealth resource center grant programs.[176] Subtitle D included an expansion of section 1135 waiver authorities for Medicare telehealth services during the emergency period by authorizing telehealth waivers other requirements under section 1834(m) of the Act and authorizing payment Medicare services delivered using telehealth furnished by FQHCs and RHCs during the emergency period.[177]

Consolidated Appropriations Act, 2021 (P.L. 116-26). On December 27, 2020, the Consolidated Appropriations Act of 2021 was signed into law. The law provided $3 billion to the pandemic relief fund and included $30 billion for the federal government to assist with purchasing and administering COVID-19 vaccines and therapeutics, and provided $8.7 billion to the CDC to administer, monitor, and track coronavirus vaccines and ensure appropriate distribution and access.[178]

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[166] Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020, Pub. L. No. 116-123.
[167] Ibid.
[168] Ibid.
[169] Ibid,div. B, § 201, 134 Stat. 155.
[170] Ibid,div. B, § 201, 134 Stat. 156.
[171] Families First Coronavirus Response Act, 2020, Pub. L. 116-127.
[172] Ibid.
[173] Ibid, div. F, § 6001, 134 Stat. 201.
[174] Coronavirus Aid, Relief, and Economic Security (CARES) Act, 2020, Pub. L. No. 116-136, 134 Stat. 281.
[175] Ibid.
[176] Ibid, title III, § 3001, 134 Stat. 360.
[177] Ibid, title III, § 3703-3704, 134 Stat. 416 (Mar. 27, 2020).
[178] Consolidated Appropriations Act of 2021, 2020, Pub. L. No. 116-200, div. H, title II, 134 Stat. 1567.

American Rescue Plan Act (ARPA) (P.L. 117-2). The ARPA was enacted on March 11, 2021 and provided funding for quality improvement organizations to carry out infection control and vaccination uptake support in Medicare-certified nursing homes and to establish and implement strike teams to respond to COVID-19 in Medicare-certified and Medicaid-certified nursing homes. [179,180] This law also provided $8.5 billion for payments to rural Medicare and Medicaid providers for health care–related expenses and lost revenue attributable to COVID-19.[181] Subtitle L provided that the Secretary may temporarily waive or modify the application of certain Medicare requirements with respect to ambulance services furnished during certain emergency periods.[182] Subtitle K of the Act provided mandatory coverage of COVID-19 vaccines and administration and treatment under CHIP,[183] and Subtitle J provided mandatory coverage of COVID-19 vaccines and administration and testing and treatment under Medicaid, and additional support for Medicaid HCBS.[184]

Consolidated Appropriations Act, 2023 (P.L. 117-328). The Consolidated Appropriations Act, 2023 included provisions related to the COVID-19 PHE and was, signed into law on December 29, 2022. Division FF, Title II contained health provisions to improve public health preparedness and response capacity and vaccine distribution plans.[185]

[179] American Rescue Plan Act of 2021, Pub. L. No. 117-2, title IX, 135 Stat. 208.
[180] Ibid, § 9818, 135 Stat. 218.
[181] Ibid, subtitle N, § 9911, 135 Stat. 236.
[182] Ibid, § 9832, 135 Stat. 221.
[183] Ibid, § 9821-9822, 135 Stat. 219.
[184] Ibid, § 9811 and 9817, 135 Stat. 208.
[185] Consolidated Appropriations Act of 2023, 2022. Pub. L. No. 117–328, div. FF, title II, § 2001, 136 Stat. 5752.

Appendix H. Medicare COVID-19 PHE Waiver Requests: Triage Process

As described in Section III of the Report, multiple teams and workgroups collaborated across CMS to process the large volume of waiver requests (over 273,000) received during the COVID-19 PHE. In addition to the COVID-19 Workgroup, these collaborations included:

- CMS Waiver Request Team that identified, organized, sorted, and categorized requests based on various factors such as provider type, location, date the request was submitted, pending time (also known as "aging information"), blanket waiver (bundle), and whether an individual waiver was approved, denied, or withdrawn. Most requests were individual waivers that CMS reviewed to determine next steps.
- Rapid Response Team that reviewed and escalated individual waiver requests that did not fall into an approved blanket waiver for further review and policy decisions by the COVID-19 Workgroup, and by CMS senior leadership as appropriate.
- Senior Clinicians' Council that reviewed waivers for clinical impact.

When individual section 1135 waiver requests were received, they were rapidly evaluated to determine if the request was covered by an approved blanket waiver. If the request was already covered, it was processed as a request covered by an approved blanket waiver and the submitter would be informed that no additional permission was needed. If the individual waiver request was not covered by an approved blanket waiver at that time, the CMS Waiver Request Team would send the request to the Escalation Analyst, who would review the request, obtain additional information, and collaborate with others at CMS to determine if the request violated health or safety compliance requirements. The Escalation Analyst/Rapid Response Team would then bring these individual waiver requests to the COVID-19 Workgroup with its recommendation based on the information gathered. The COVID-19 Workgroup would then make policy decisions about whether each request could be resolved under current law such as an existing regulation, sub-regulatory guidance, or condition of participation. If the individual request was not covered by an approved blanket waiver but could be resolved under current law, it was approved as such, and the submitter was notified. Most individual waiver requests (approximately 230,000) were approved in this way. However, if an individual waiver request was not covered by an approved blanket waiver or could not be resolved under current law, it was escalated for further review and decision by CMS' senior leadership.

Approximately 325 requests that were not covered by an approved blanket waiver were approved as individual waivers. Many individual waiver requests were submitted multiple times. Multiple submissions often were withdrawn by the submitter once they realized that their request was already processed or decided to submit a different request that better addressed their needs.

SharePoint management of income waiver requests. To accommodate the volume and scope of waiver requests, CMS rapidly pivoted to a new system to review and process waiver requests in a consistent, organized, structured, efficient, and timely manner nationwide. As an initial step, CMS created a SharePoint[186] system to manage the incoming Medicare section 1135 waiver requests; hundreds of employees from across CMS worked in the SharePoint system 24-hours a day, seven days a week. One reflection of the rapid growth was seen in the list of COVID-19 Emergency Declaration Blanket Waivers (BW) for Health Care Providers, which was less than one-half page in length before the PHE.

From SharePoint to SNOW web portal. SharePoint had the benefit of allowing CMS to more effectively coordinate across the agency to respond to the pandemic; however, SharePoint did not allow receipt of section 1135 waiver requests in a standardized format, which made it difficult to track and respond quickly. For example, it was common for CMS to contact the requestor multiple times due to critical information missing from the request. While the bulk of the individual waiver requests submitted in 2020 were processed

[186] SharePoint is a Microsoft web-based application that allows organizations to store and organize content and information, which includes documents, images, videos, news, links, lists of data, web pages, and tasks.

using the SharePoint system, in January 2021, CMS launched the SNOW system using the ServiceNow® platform,[187] a web-based portal that allowed for more seamless triage and processing along with reporting on what had occurred. This online web portal allowed submitters to request a section 1135 waiver or flexibility, or to submit an inquiry, by providing very brief contact and organizational information guided by drop down menu items and check-the-box items. The portal became a central place for health care providers, states, local governments, and others to apply for—and for CMS to process—Medicare section 1135 waiver requests. CMS also established a page on its website to keep stakeholders up to date with the list of blanket waivers and flexibilities as well as the waiver process.[188]

The system of identifying, organizing, sorting, and categorizing section 1135 waiver requests enabled the CMS Waiver Request Team to generate reports for the Office of the Administrator and CMS' senior leadership that identified how many requests had been received to date, how many had been approved or denied, and how many were pending. Pending section 1135 waiver requests were tracked by how long they had been pending. The pending waiver requests were then sorted by type of health care provider (for example, home health agencies, hospitals, and therapists) for CMS to determine whether the underlying individual waiver request could be converted to a blanket waiver or not.

[187] Centers for Medicare & Medicaid Services, "CMS 1135 Waiver/Flexibility Request and Inquiry Form," accessed January 10, 2024.
[188] Centers for Medicare & Medicaid, "Coronavirus Waivers and Flexibilities," last modified September 6, 2023.

Appendix I. Status of COVID-19 PHE Section 1135 Medicare & Medicaid Waivers and Flexibilities

Description	Approach	Status
Vaccines and Therapeutics		
FDA EUA declaration for drugs and biologicals with respect to COVID-19, including vaccines, monoclonal antibodies and oral antivirals	Regulation	EUAs for vaccines and treatments remain authorized until the EUA is revoked or the applicable EUA declaration pursuant to section 564 of the U.S. Food, Drug, and Cosmetic Act is terminated. The EUA declaration for COVID-19 treatments is distinct from, and not dependent on, the PHE.[189]
Required LTC facilities to educate staff and residents about vaccine and offer vaccination	Regulation	Made permanent
Required vaccination for staff among Medicare- and Medicaid-certified providers and suppliers	Regulation	Ended at conclusion of the PHE
COVID-19 Testing		
Updated Medicare payments for specimen collection for purposes of COVID-19 testing	Regulation	Ended at conclusion of the PHE
Issued limits on COVID-19 and related testing without an order and expansion of testing authority under Medicare	Regulation	Ended at conclusion of the PHE
Required LTC facilities to conduct testing for staff and residents	Regulation	Ended at conclusion of the PHE
Increased Medicare payments for high-throughput tests	Administrator's Ruling	Ended at conclusion of the PHE
Required price transparency for diagnostic testing	Regulation	Ended at conclusion of the PHE
Expedited review and processing of CLIA certificate applications for laboratories	Sub-regulatory guidance	Ended at conclusion of the PHE
Telehealth		
Waived requirements specifying the types of clinicians eligible to provide telehealth for Medicare covered services	Section 1135 waiver	Extended until December 31, 2024
Waived Medicare telehealth geographic and location restrictions for Medicare clinicians and beneficiaries	Section 1135 waiver	Extended until December 31, 2024

[189] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends

Description	Approach	Status
Added services to the Medicare Telehealth Services List (either temporarily or permanently)	Regulation/Sub-regulatory guidance	No expiration for services temporarily added (ongoing).
Allowed some Medicare covered services to be furnished via audio-only modalities	1135 waiver	Extended until December 31, 2024
Waived frequency limitations for certain Medicare covered services furnished via telehealth	IFC	Extended until December 31, 2024
Allowed clinicians to provide e-visits and remote physiological monitoring services to new Medicare patients without an in-person visit	IFC	Ended at the conclusion of the PHE
Allowed clinicians billing Medicare for telehealth to report the place of service code that would have been used had the service been furnished in person	IFC	Ended on December 31, 2023
Allowed RHCs and FQHCs to furnish telehealth for Medicare covered services	CAA, 2023	Extended until December 31, 2024
Emergency Reporting		
Decreased reporting requirements for quality programs	Regulatory	Terminated (date varies by program)
Required COVID-19 data reporting from all hospitals	Regulation	Ended on April 30, 2024; Finalized new streamlined requirements effective October 1, 2024
Surge Capacity		
Blanket waivers of sanctions under the physician self-referral law for COVID-19 Purposes	Section 1135 waiver	Ended at the conclusion of the PHE, unless otherwise noted
Allowed CAH establishment of surge sites in non-rural areas	Section 1135 waiver	Ended at the conclusion of the PHE.
Waived CAH off-campus and co-location requirements	Section 1135 waiver	Ended at the conclusion of the PHE
Waived CAH bed count limit	Section 1135 waiver	Ended at the conclusion of the PHE
Waived requirement for a 3-day hospitalization preceding a SNF stay	Section 1135 waiver	Ended at the conclusion of the PHE
Hospital Without Walls program	Section 1135 waiver	Ended at the conclusion of the PHE
Acute Care Hospital at Home program	Section 1135 waiver	Extended until December 31, 2024
Long-Term Care		
Allowed use of non-SNF buildings as SNFs	Section 1135 waiver	Terminated June 6, 2022
Waived certain conditions of participation and certification requirements for nursing facilities	Section 1135 waiver	Terminated June 6, 2022
Allowed use of non-traditional spaces for resident rooms	Section 1135 waiver	Terminated June 6, 2022

Description	Approach	Status
Allowed transfer of patients to different facilities dedicated to treating patients with/without COVID-19	Section 1135 waiver; sub-regulatory guidance	Terminated May 10, 2021
Suspended certain staff training and certification requirements	Section 1135 waiver	Conditionally terminated[190]
Enabled physicians to delegate more tasks, including visits, to non-physicians	Section 1135 waiver	Terminated May 7, 2022
Established Requirements for LTCs to report new infections, case counts, and vaccination/treatment data	Regulation	Extended until December 31, 2024; Finalized new streamlined requirements effective January 1, 2025
Require testing of COVID-19 staff	Regulation	Ended on May 11, 2024

[190] Facilities that still experience barriers to nurse aide certification may still work under a waiver.

Appendix J. Status of Provisions, Waivers and Flexibilities Continuing Beyond the COVID-19 PHE

Status of provisions tied to waivers and flexibilities. Across the six key topics covered in this report, several provisions are set to remain beyond the end of the COVID-19 PHE. Exhibit J.1 presents a summary list, based on publicly available guidance that CMS has posted on its website.

Exhibit J.1: Status of Provisions, Waivers and Flexibilities Continuing Beyond the COVID-19 PHE

Provision	Coverage
Vaccines and Therapeutics[191,192]	
COVID-19 vaccines and their administration will continue to be available without cost-sharing when furnished by a participating health care provider.	{Medicare}
There is no change in Medicare coverage of treatments for those exposed to COVID-19 once the PHE ends, and in cases where cost-sharing and deductibles apply now, they will continue to apply. Monoclonal antibodies used for post-exposure prophylaxis or treatment of COVID-19 will eventually be paid as Part B drugs, effective January 1 of the year following the year in which the EUA declaration ends.	{Medicare}
Generally, the end of the COVID-19 PHE does not change access to oral antivirals, such as Paxlovid and Lagevrio.	{Medicare}
CMS will continue to cover and pay for monoclonal antibodies used for PrEP of COVID-19, and their administration, under the Part B preventive vaccine benefit, if they meet applicable coverage requirements.	{Medicare}
CMS will continue to pay approximately $40 per dose for administering COVID-19 vaccines in most outpatient settings for Medicare beneficiaries through the end of the calendar year in which the Secretary ends the EUA declaration for drugs and biologicals with respect to COVID-19. Effective January 1 of the year following the year in which the EUA declaration ends, CMS will set the payment rate for administering COVID-19 vaccines to align with the payment rate for administering other Part B preventive vaccines, that is, approximately $30 per dose.[193]	{Medicare}
Oral antivirals procured by the USG and provided to pharmacies are given to patients at no cost. This process will continue while oral antivirals are being procured by the USG. CMS has permitted Part D sponsors to pay pharmacy claims for dispensing fees for USG-procured oral antiviral drugs for treatment of COVID-19 without enrollee cost-sharing, and report prescription	{Medicare Part D}

[191] Information in this section based on CMS, CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency | CMS and CMS, Long-Term Care Hospitals & Extended Neoplastic Disease Care Hospitals: CMS Flexibilities to Fight COVID-19.
[192] CMS, "Coverage and Payment of Vaccines and Vaccine Administration under Medicaid, the Children's Health Insurance Program, and Basic Health Program," accessed December 20, 2024.
[193] CMS. Nov 2023 CMS FAQs on End of the CV19 PHE.

Provision	Coverage
drug events for the dispensing fee claims.[194, 195] Additionally, the agency has strongly encouraged Part D sponsors to pay dispensing fees for these drugs that may be higher than a sponsor's usual negotiated dispensing fees, given the unique circumstances during the COVID-19 PHE. This flexibility has continued following the end of the COVID-19 PHE while USG-procured product remains available.	
ARPA required coverage of COVID-19 vaccines and their administration, without cost-sharing, for all CHIP beneficiaries and nearly all Medicaid beneficiaries, including most eligibility groups receiving limited Medicaid benefit packages under the state plan or a section 1115 demonstration. ARPA also established a temporary Medicaid and CHIP federal matching percentage of 100 percent for COVID-19 vaccines and their administration. The ARPA COVID-19 vaccination coverage requirement and federal matching percentage ended on September 30, 2024 (the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE). After that date, many Medicaid-eligible children will receive coverage of COVID-19 vaccinations included on the CDC/ACIP pediatric immunization schedule, pursuant to the Early and Periodic Screening, Diagnostic and Treatment benefit requirements, while many Medicaid-eligible adults will receive coverage of FDA-approved ACIP-recommended COVID-19 vaccines pursuant to the Inflation Reduction Act (P.L. 117-169) vaccine coverage mandate. State expenditures on COVID-19 vaccine doses and their administration would be matched at the applicable state FMAP.	{Medicaid and CHIP}
COVID-19 Testing[196]	
Access to receive COVID-19 PCR and antigen tests will continue with no cost-sharing when the test is ordered by a physician or certain other health care providers, such as physician assistants and certain registered nurses, and performed by a laboratory.	{Medicare}
Individuals enrolled in Medicare Advantage (MA) plans will receive COVID-19 PCR and antigen tests when the test is covered by Medicare, but their cost-sharing may have changed when the PHE ends. Access to free over the counter COVID-19 tests ended with the end of the PHE. However, some Medicare Advantage plans may continue to provide coverage of over-the-counter COVID-19 tests or reduced cost sharing for COVID-19 PCR and antigen tests as a supplemental benefit.	{Medicare} By law, original Medicare does not generally pay separately for over-the-counter services and tests.

[194] CMS, Medicare Advantage and Part D Plans: CMS Flexibilities to Fight COVID-19
[195] https://www.cms.gov/files/document/commercialcovid19oralantiviralsmemofinal.pdf
[196] Information in this section based on CMS, CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency | CMS.

Provision	Coverage
The ARPA-mandated coverage for COVID-19 testing ended on September 30, 2024 (the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE). After that date, coverage of COVID-19 testing may vary by state. With the end of the PHE, Medicaid coverage to uninsured individuals from 18 states and territories for COVID-19 testing, vaccines, and treatment also ended. Regulations at 42 CFR. § 440.30(a) require that coverage under the Medicaid laboratory and X-ray services benefit be for services ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of his or her practice as defined by state law or ordered by a physician but provided by a referral laboratory. 42 CFR. § 440.30(b) specifies that Medicaid will cover laboratory and X-ray services only if provided in an office or similar facility other than a hospital outpatient department or clinic, and 42 CFR. § 440.30(c) specifies that Medicaid will cover these services only if they are furnished by a laboratory that meets the requirements of 42 CFR. part 493. 42 CFR § 440.30(d) specifies that during the COVID-19 PHE defined in 42 CFR. § 400.200 or any future PHE resulting from an outbreak of communicable disease, and during any subsequent period of active surveillance, Medicaid coverage is available for laboratory tests and X-ray services that do not meet conditions specified in § 430.30(a) or (b), if the purpose of such laboratory and X-ray services is to diagnose or detect SARS–CoV–2, antibodies to SARS–CoV–2, COVID–19, or the communicable disease named in the PHE or its causes, and if the deviation from the conditions specified in § 430.30(a) or (b) is intended to avoid transmission of the communicable disease. A period of active surveillance is defined as an outbreak of communicable disease during which no approved treatment or vaccine is widely available, and it ends on the date the Secretary terminates it, or the date that is two incubation periods after the last known case of the communicable disease, whichever is sooner. Additionally, during the COVID-19 PHE defined in 42 CFR. § 400.200 or any future PHE resulting from an outbreak of communicable disease, and during any subsequent period of active surveillance, Medicaid coverage is available for laboratory processing of self-collected laboratory test systems that are authorized by the FDA for home use, if available to diagnose or detect SARS–CoV–2, antibodies to SARS–CoV–2, COVID–19, or the communicable disease named in the PHE or its causes, even if those self-collected tests would not otherwise meet the requirements of § 430.30(a) or (b), provided that the self-collection of the test is intended to avoid transmission of the communicable disease. If a laboratory processes a self-collected test system that is authorized by the FDA for home use, and the test system does not meet the conditions in § 430.30(a), the laboratory must notify the patient and the patient's physician or	{Medicaid, CHIP} The lab and X-ray benefit regulation allows states to apply paragraph (d) for future public health emergencies resulting from an outbreak of communicable disease and for subsequent periods of active surveillance.

Provision	Coverage
other licensed non-physician practitioner (if known by the laboratory), of the results.	
Telehealth[197]	
The CAA, 2023 extended the telehealth flexibilities (in the CAA 2022) through December 31, 2024. The flexibilities include: • Removing geographic restrictions, to allow any site within the United States that the telehealth individual is located in to serve as an originating site for telehealth services that Medicare pays for, including the individual's home and non-rural areas. • Delaying in-person requirements for mental health services furnished via telehealth. Certain telehealth visits could be delivered via audio-only (such as a telephone) if someone were unable to use both audio and video. • Expanding the definition of telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists, and qualified audiologists. • Continuing to pay for telehealth services furnished by RHCs and FQHCs using the methodology established for such services during the COVID-19 PHE.	{Medicare} After December 31, 2024, when these flexibilities expire, some ACOs may offer telehealth services that allow clinicians to care for patients who are located in any geographic area and in their homes. For CY 2024, CMS finalized refinements to their process for analyzing requests received for the addition of services to the Medicare Telehealth Services List, including a determination on whether the requested services should be added permanently or provisionally. CMS also finalized addition of the Social Determinants of Health Risk Assessments on a permanent basis.
Telehealth flexibilities are not tied to the end of the PHE and have been offered by many state Medicaid programs long before the pandemic. Coverage will ultimately vary by state. CMS encourages states to continue to cover Medicaid and CHIP services when they are delivered via telehealth.	{Medicaid, CHIP}

[197] Information in this section based on CMS, CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency | CMS.

Appendix K: Transition After the End of the COVID-19 PHE—Section 1135 Medicaid Waivers

As noted in Section III of the Report, states received variable, temporary flexibilities through section 1135 waiver authority. As the end of the PHE approached, each state evaluated their section 1135 Medicaid waivers to determine actions required.[198] As states shifted to routine operations for Medicaid and CHIP, they were required to resume compliance with regular program requirements, either immediately upon the conclusion of the PHE or over a period of time in accordance with section 5131 of subtitle D of title V of division FF of the Consolidated Appropriations Act, 2023 (CAA, 2023) and as further detailed in CMS guidance, including State Health Official (SHO) letter #20-0004. CMS conducted outreach to the states, through All State Calls and one-on-one calls during which CMCS provided guidance and technical assistance.

Actions required of the states included the following:

- **Informing beneficiaries and providers.** States informed affected providers and beneficiaries about the end of waivers and related flexibilities, to ensure a smooth transition to routine operations. When a state ends an authority that results in a termination, reduction, or change in benefits or services, it must generally provide at least 10-days advance notice of the change and outline the beneficiary's right to a Medicaid fair hearing or a CHIP review. Table C-2 in the State Health Official (SHO) letter #20-0004 lists each section 1135 waiver, the action required to end that waiver, and the time period for completion of the action.
- **Revising timeframes to request a fair hearing.** CMS granted states flexibility to allow applicants or beneficiaries more than 90 days to request a fair hearing.[199] The extended time periods for individuals to request fair hearings varied by state.
- **Finalizing provider enrollments.** As noted in the Report, states responded to anticipated workforce shortages by using section 1135 Medicaid waiver authority to delay revalidation of providers, for provisional and temporary enrollment of providers enrolled with another Medicaid agency or Medicare, and/or to relax certain provider screening requirements for providers not already enrolled with another Medicaid agency or Medicare (for example, related to payment of an application fee at 42 CFR § 455.460 and fingerprint-based criminal background checks at 42 CFR § 455.434). Providers were required to meet a minimum set of requirements, as reflected in the waiver approval language.
    - For states that paused revalidations, the revalidation of providers was expected to resume with the end of the COVID-19 PHE. Where revalidation due dates occurred during the PHE, a state could delay the revalidation due date by the amount of time the PHE was in place, with an additional six months of lead time to allow for notifying the provider about the new revalidation due date. In addition, states were granted another six months to complete revalidations otherwise due within six months after the end of the PHE.
    - States have had up to six months from the end of the PHE (including any extensions) to cease payment to providers not fully screened and enrolled. CMS requested written assurance from states and territories that they have taken the necessary steps to complete the screening of provisional enrollments.
- **Completing level of care assessments.** Many states used section 1135 waivers to delay initial level of care determinations for participants in 1915(c) waivers, 1915(k) state plan programs, or initial functional needs assessments in 1915(i) and 1915(k) state plan programs. States were required to complete all initial determinations delayed by the section 1135 waiver within 90 days of the end of the PHE and to adhere to the requirement that new participants have their initial determinations completed prior to the provision of any service.

[198] Information in this Appendix is based on CMS, Planning for the Resumption of Normal State Medicaid, CHIP, and BHP Operations Upon Conclusion of COVID-19 PHE, Letter to State Health Officials, December 20, 2020.
[199] Section 42 CFR. §431.221(d) requires states to choose a reasonable timeframe for individuals to request a fair hearing, not to exceed 90 days from the date the notice is mailed for eligibility or fee-for-service appeals.

Appendix L: Regulatory Changes to the Medicare Shared Savings Program in Response to the COVID-19 PHE

CMS used other program specific authority in addition to section 1135 waiver authority to modify certain Medicare payment provisions during the COVID-19 PHE, and rulemaking was often necessary. CMS promulgated numerous rules modifying the Shared Savings Program in response to the COVID-19 PHE. In the Interim Final Rule with Comment (IFC) titled Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (hereafter "COVID-19 IFC"), which was issued on March 31, 2020, CMS removed a restriction that prevented the application of the Shared Savings Program "extreme and uncontrollable circumstances" policy for disasters that occur during the quality reporting period if the reporting period is extended. Removal of this restriction offered relief under the Shared Savings Program to all ACOs that may have been unable to completely and accurately report quality data for 2019 due to the COVID-19 PHE (85 FR 19267 and 19268).

In the May 8, 2020 Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program IFC (85 FR 27573 through 27587) (hereafter "May 8th COVID-19 IFC"), CMS modified Shared Savings Program policies to: 1) allow ACOs whose agreement periods were scheduled to expire on December 31, 2020, the option to extend their agreement period by 1 year; 2) allow ACOs in the BASIC track's glide path the option to elect to maintain their level of participation for Performance Year (PY) 2021; 3) adjust certain program calculations to remove payment amounts for episodes of care for treatment of COVID-19; and 4) expand the definition of primary care services for purposes of determining beneficiary assignment (to include codes for additional services delivered, remotely such as virtual check-ins, e-visits, and telephonic communication). CMS also clarified the applicability of the Shared Savings Program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the COVID-19 PHE that began in January 2020. Further, CMS addressed the applicability of these policies to ACOs participating in the Medicare ACO Track 1+ Model (Track 1+ Model).

1. Shared Savings Program Telehealth Waiver and Skilled Nursing Facility 3-Day Rule Waiver

a. Telehealth

With the passage of the Bipartisan Budget Act of 2018, new flexibilities were granted for physicians and practitioners in certain ACOs in the delivery of services through telehealth for dates of service on or after January 1, 2020. Providers and suppliers in ACOs in a two-sided risk track that chose prospective assignment could bill for certain services without the geographic limitations that usually apply to FFS telehealth coverage. Also, the home of the beneficiary could qualify as an originating site for these telehealth services.

During the COVID-19 PHE, the Secretary used section 1135 waiver authority to create flexibilities in the requirements of section 1834(m) of the Act and 42 CFR § 410.78 for use of interactive telecommunications systems to furnish telehealth services. This allowed clinicians to deliver more services to beneficiaries via telehealth, caring for their patients while mitigating the risk of the spread of the virus. During the COVID-19 PHE, all beneficiaries could receive Medicare telehealth and other communications technology-based services at any location. In addition, after the PHE ended, the CAA, 2023 provided an extension for some telehealth flexibilities through December 31, 2024.

The Shared Savings Program telehealth policies did not supersede the waiver authority under section 1135 of the Act, and the flexibilities allowed under the section 1135 waivers applied to services furnished by providers and suppliers participating in ACOs.

b. SNF 3-day Rule Waiver

The Shared Savings Program SNF 3-Day Rule Waiver waives the requirement for a 3-day inpatient hospital stay prior to a Medicare-covered, post-hospital, extended-care service for eligible beneficiaries if certain conditions are met. Only Shared Savings Program ACOs currently participating in or applying to certain Shared Savings Program performance-based risk tracks could apply for and, if approved, use a waiver of the SNF 3-Day Rule.

On March 30, 2020, CMS issued the COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers in which, among other waivers, CMS temporarily waived the requirement for a three-day prior inpatient hospitalization for coverage of a SNF stay using the statutory flexibility under Section 1812(f) of the Act. This waiver provided temporary emergency coverage of SNF services without a qualifying 3-day hospital stay. In addition, for certain beneficiaries who exhausted their SNF benefits, it authorized a one-time renewal of SNF coverage without first having to start and complete a 60-day "wellness period" (that is, the 60-day period of non-inpatient status that is normally required to end the current benefit period and renew SNF benefits).[200]

The Shared Savings Program SNF 3-day waiver did not supersede the statutory flexibility under Section 1812(f) of the Act and flexibilities were applied to all SNFs, regardless of ACO affiliation or participation.

2. Changes made to Shared Saving Program Quality Reporting Policy

In response to the COVID-19 PHE, during CY 2020, the Shared Savings Program extended the MIPS quality reporting period for 2019 and modified the Shared Savings Program's "extreme and uncontrollable circumstances" policy to eliminate the restriction that it applied only if the quality reporting period was not extended (COVID-19 IFC (85 FR 19267 – 19268)). The modifications to the regulations in 42 CFR § 425.502(f) were effective as of March 31, 2020. Additionally, in December 2020, for PY 2021 and subsequent PYs, CMS finalized the continued use of an updated "extreme and uncontrollable circumstances" policy under 42 CFR § 425.512(b) that set forth an alternative approach to calculate the quality score for ACOs affected by extreme and uncontrollable circumstances (85 FR 84744 - 84747).

The Shared Savings Program also modified the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs survey reporting requirements for PY 2020 to waive the CAHPS for ACOs reporting requirement for PY 2020 and to assign all ACOs automatic credit for each CAHPS survey measure within the patient/caregiver experience domain (85 FR 84794). Modifications to the regulations in 42 CFR § 425.500(d) were effective as of January 1, 2021.

3. Changes made to Shared Saving Program Participation Options

CMS allowed ACOs to maintain or "freeze" their PY 2020 participation options so that any ACOs required to renew their participation for a new agreement period starting on January 1, 2021, were not burdened with meeting application deadlines; in addition, ACOs participating in the BASIC track's glide path could forgo the requirement to advance to the next level for PY 2021 (85 FR 27574 - 27576; 85 FR 84763 - 84769). CMS subsequently allowed ACOs in the BASIC track's glide path to forgo the requirement to advance to the next level for PY 2022, allowing them a second "freeze" option (86 FR 45503 - 45506).

4. Changes made to Shared Saving Program Beneficiary Assignment Methodology

In response to the COVID-19 PHE, CMS finalized updates to the Shared Savings Program regulations related to beneficiary assignment to include additional primary care service codes used to determine beneficiary assignment when the assignment window (as defined at § 425.20) for a benchmark or PY includes any month(s) during the COVID-19 PHE (as defined in § 400.200). The codes included the

[200] CMS. https://www.cms.gov/files/document/long-term-care-facilities-cms-flexibilities-fight-covid-19.pdf (Accessed on October 23, 2024)

following: 1) CPT codes 99421, 99422, and 99423 (online digital evaluation and management services (e-visit)); 2) CPT codes 99441, 99442, and 99443 (telephone evaluation and management services); and (3) HCPCS code G2010 (remote evaluation of patient video/images) and HCPCS code G2012 (virtual check-in) (85 FR 84785 through 84793). Under this provision, the CPT codes and HCPCS codes included in the applicable definition of primary care services at 42 CFR § 425.400(c)(1) continued to apply for purposes of determining beneficiary assignment under 42 CFR § 425.402.

The expanded definition of primary care services was also applicable to beneficiary assignment for Track 1+ Model ACOs in the same way it has applied to Shared Savings Program ACOs under prospective assignment.

5. Changes made to Shared Saving Program Calculations

a. Benchmark Methodology Applied to Optional Fourth PY for ACOs that Elect 1-year Extension of Agreement Period Expiring December 31, 2020

CMS revised 42 CFR § 425.200(b)(3)(ii) to allow ACOs that entered a first or second agreement period with a start date of January 1, 2018, to elect to extend their agreement period for an optional fourth PY, spanning 12 months from January 1, 2021, to December 31, 2021. This election to extend the agreement period was voluntary, and an ACO could choose not to make this election, concluding its participation in the Shared Savings Program with expiration of its current agreement period on December 31, 2020 (85 FR 27574 and 27575 and 85 FR 84765 through 84767).

ACOs that chose to extend their existing agreement period for one year were subject to the applicable benchmarking methodology under § 425.602 or § 425.603. These ACOs' historical benchmarks were based on the three years prior to their existing agreement period. The ACOs were financially reconciled for PY 2021 according to the methodology for calculating shared savings or shared losses applicable to the ACO under the terms of the participation agreement in effect for PY 2021.

b. Extreme and Uncontrollable Circumstances Policy Mitigating Shared Losses During the COVID-19 PHE

The Secretary's declaration of the COVID-19 PHE in January 2020 triggered the Shared Savings Program's "extreme and uncontrollable circumstances" policy to mitigate shared losses. The policy applied beginning in January 2020 and applied nationwide for the duration of the COVID-19 PHE, as defined in 42 CFR § 400.200. The COVID-19 PHE applied to all counties in the country; therefore, 100 percent of assigned beneficiaries for all Shared Savings Program ACOs resided in an affected area.

Shared losses were mitigated for all ACOs participating in a performance-based risk track, including Track 2, the ENHANCED track, Levels C, D, and E of the BASIC track, and the Track 1+ Model:

1. For PYs 2020 (January through December 2020), 2021 (January through December 2021), and 2022 (January through December 2022) the COVID-19 PHE covered the full year, and any shared losses an ACO incurred for PYs 2020, 2021, or 2022 were mitigated completely. ACOs did not owe any shared losses.

2. For PY 2023 (January through December 2023), the COVID-19 PHE covered 5 months (January through May 2023) and shared losses incurred by ACOs were reduced by five-twelfths.

Further, in the portion of the PY following the end of the COVID-19 PHE, the reduction of shared losses would be extended for ACOs with assigned beneficiaries residing in areas affected by other events deemed by CMS to be extreme and uncontrollable circumstances.

c. Adjustments to Shared Savings Program Calculations for Episodes of Care for Treatment of COVID-19

An episode of care for treatment of COVID-19 is identified based on either of the following:

- Discharges for inpatient services eligible for the 20 percent adjustment under section 1886(d)(4)(C) of the Act.
- Discharges for acute care inpatient services for treatment of COVID-19 from facilities that are not paid under the inpatient prospective payment system (IPPS), such as CAHs, when the date of discharge occurs within the PHE as defined in 42 CFR § 400.200.

Inpatient claims could trigger an episode of care for treatment of COVID-19 whether the claim is submitted by an IPPS or non-IPPS provider. Claims that did not meet these criteria would not trigger an episode of care for treatment of COVID-19.

Episode months include:

- Calendar month of admission;
- Calendar month of discharge;
- Any calendar months between calendar month of admission and calendar month of discharge; and
- Calendar month following calendar month of discharge.

Each episode starts at the beginning of the admission month and ends at the close of the month following the discharge month.[201]

Shared Savings Program calculations were adjusted to exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID-19 when establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining PY expenditures.

[201] Fleisher LA, Schreiber M, Cardo D, Srinivasan A. Health Care Safety during the Pandemic and Beyond - Building a System That Ensures Resilience. N Engl J Med. 2022 Feb 17;386(7):609-611. doi: 10.1056/NEJMp2118285. Epub 2022 Feb 12. PMID: 35148040.